

FORMULAR INFORMATIV DESPRE OFERTANT

1. Denumirea **MEDIST GRUP SRL**

2. Codul fiscal **1018600004516**

3. Adresa sediului central **mun. Chișinău, str. Bănulescu Bodoni, 25 oficiul 33**

4. Telefon **/022/ 84-94-95**

E-mail office@medist.md

5. Certificatul de înregistrare

1018600004516 din 02.02.2018

(numărul, data înregistrării)

I. P. Agenția Servicii Publice

(instituția emitentă)

6. Obiectul de activitate, pe domenii:

- **Comerț cu ridicata al produselor farmaceutice;**
- **Comerț cu ridicata nespecializat;**
- **Repararea echipamentelor electronice și optice;**
- **Activități de testare și analize tehnice;**
- **Comerț cu amănuntul al articolelor medicale și ortopedice, în magazine specializate;**
(în conformitate cu prevederile din statutul propriu)

7. Rechizitele bancare:

BC Victoriabank SA, Filiala nr.26 Chișinău

Codul bancii: VICBMD2X469

IBAN (MDL): MD57VI022242600000269MDL

Data completării: **28.11.2024**

Semnat: _____

Nume: **Gabriela-Cristina Anghel**

Funcția în cadrul firmei: **Directoare administrativă**

Denumirea firmei și sigiliu: **Medist Grup SRL**

Digitally signed by Anghel Gabriela-Cristina

Date: 2024.11.28 18:04:59 EET

Reason: MoldSign Signature

Location: Moldova

MOLDOVA EUROPEANĂ



Anexa nr. 2
la Regulamentul cu privire la achizițiile
publice de valoare mică

DECLARAȚIE DE ELIGIBILITATE

Către IMSP SCR „Timofei Moșneaga”

Stimați domni,

Subsemnatul, reprezentant împuternicit al Medist Grup SRL, (denumirea operatorului economic) în calitate de ofertant, declar pe propria răspundere, sub sancțiunea excluderii din procedură și sub sancțiunile aplicate faptei de fals în acte publice, că nu mă aflu în una dintre situațiile prevăzute la art. 19 din Legea nr. 131/2015 privind achizițiile publice.

Mă oblig, la solicitarea autorității/entității contractante, în scopul verificării și confirmării declarației, să prezint orice document doveditor de care dispun.

Data completării 28 noiembrie 2024

Ofertant/candidat **Medist Grup SRL**

(semnătura autorizată)

I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de
drept

**Extras
din Registrul de stat al persoanelor juridice
nr. 117493 din 15.09.2023**



Denumirea completă: **Societatea cu Răspundere Limitată "MEDIST GRUP"**

Denumirea prescurtată: **"MEDIST GRUP" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată**

Numărul de identificare de stat și codul fiscal: **1018600004516**

Data înregistrării de stat: **02.02.2018**

Sediu: **MD-2012, strada Mitropolit Gavriil Bănulescu-Bodoni 25, ap. 33, mun. Chișinău,**

Republica Moldova

Genurile de activitate:

- 1. Comerț cu ridicata al produselor farmaceutice;**
- 2. Comerț cu ridicata nespecializat;**
- 3. Repararea echipamentelor electronice și optice;**
- 4. Activități de testare și analize tehnice;**
- 5. Comerț cu amănuntul al articolelor medicale și ortopedice, în magazine specializate;**

Capitalul social: **373026 Lei**

Administrator: **ANGHEL GABRIELA-CRISTINA IDNP 2017803985939**

Asociați:

- 1. MEDIST IMAGING & P.O.C. S.R.L., partea socială 6244 Euro, ce constituie 33.00%**
- 2. MEDIST LIFE SCIENCE S.R.L., partea socială 6244 Euro, ce constituie 33.00%**
- 3. MEDIST S.R.L., partea socială 6433 Euro, ce constituie 34.00%**

Beneficiari efectivi: **MANOLE IONEL, KLUMPNER CATALINA ANA, VLĂDESCU CARMEN, VLĂDESCU SEBASTIAN-ALEXANDRU**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr.220/2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de 15.09.2023

Specialist coordonator

Marina Franțuz

tel. 022-207837

Certificate of Accreditation



Radox Laboratories Limited

Proficiency Testing Provider No. 0010

**is accredited in accordance with International Standard ISO/IEC 17043:2010
- Conformity assessment - General requirements for proficiency testing**

This accreditation demonstrates technical competence for a defined scope specified in the schedule to this certificate. The schedule to this certificate is an essential accreditation document and from time to time may be revised and reissued.

The most recent issue of the schedule of accreditation, which bears the same accreditation number as this certificate, is available from www.ukas.com.

This accreditation is subject to continuing conformity with United Kingdom Accreditation Service requirements.

A handwritten signature in black ink, reading "Matt Gantley", is positioned above a horizontal line.

Matt Gantley, *Chief Executive Officer*
United Kingdom Accreditation Service

Initial Accreditation: July 4, 2002
Certificate Issued: December 9, 2019



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ПРОГРАММЫ ВНЕШНЕЙ ОЦЕНКИ КАЧЕСТВА



МЕЖДУНАРОДНАЯ СИСТЕМА ВНЕШНЕЙ ОЦЕНКИ КАЧЕСТВА RANDOX

ХАРАКТЕРИСТИКИ И ПРЕИМУЩЕСТВА

Международная система внешней оценки качества Randox RIQAS

RIQAS – крупнейшая международная система внешней оценки качества (ВОК), используемая в более чем 55000 лабораториях участницах в более чем 134 странах. Такое большое количество участников обеспечивает обширную базу данных результатов для многочисленных аналитических методов, что напрямую повышает статистическую достоверность.

Преимущества

Большая база данных результатов, полученных участниками

- Высокий уровень участия означает, что размер групп сравнения максимально увеличивается, обеспечивая, таким образом, наличие достаточного объема данных по широкому спектру приборов и методов.

Простые и удобные отчеты

- Простой одностраничный формат отчёта по каждому аналиту позволяет оценивать результаты с одного взгляда, экономя ценное время лаборатории.
- Дополнительные отчеты по группе приборов / лабораторий позволяют проводить сравнительную оценку всех аналитических систем и лабораторий, входящих в группу.
- Итоговые отчеты по окончании цикла суммируют результаты оценки за текущий цикл в сравнении с результатами предыдущего цикла, позволяя выявлять изменения в уровне качества за продолжительные периоды времени.

Экономическая эффективность

- Широкий спектр программ, включающих большой перечень аналитов позволяет сократить число отдельных программ, требуемых для охвата всего Вашего меню тестов, экономя время и средства лаборатории.
- Наличие для ряда программ вариантов с сокращенным перечнем аналитов обеспечивает большую гибкость и соответствие требованиям лабораторий разного размера и бюджета.
- Возможность регистрации до пяти приборов на одну программу без дополнительной платы для проведения их индивидуальной и сравнительной оценки.

Частота исследований

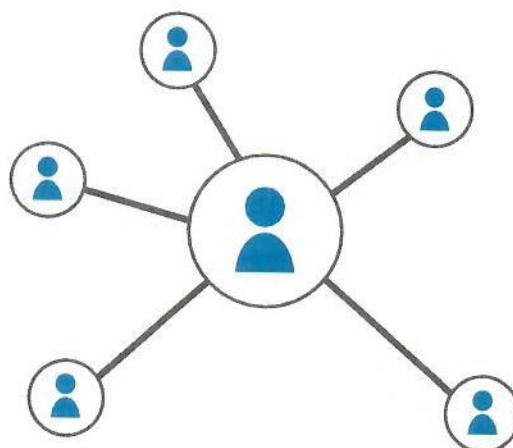
- Частое проведение ВОК позволяет оперативнее выявлять ошибки в работе тест-систем и проводить корректирующие действия, минимизируя последствия для лаборатории.
- Короткий цикл обработки результатов - менее, чем 72 часа для большинства отчетов позволяет раньше выполнить необходимые корректирующие действия, что потенциально снижает количество повторных анализов образцов пациентов в случае выявления ошибок в КК.

Высокое качество образцов

- Образцы, охватывающие все клинически значимые уровни аналитов позволяют выявлять сдвиги в концентрациях, помогая
- Образцы человеческого происхождения не содержат добавок и консервантов, влияющих на результаты измерения, увеличивают уверенность в том, что результаты ВОК адекватно отражают уровень правильности результатов для образцов пациентов.
- Для ряда аналитов и партий контрольных образцов программы по клинической химии предоставляются значения, полученные референсными методами.

Высокая авторитетность

- Программы RIQAS признаны национальными и международными органами аккредитации по всему миру.
- Сертификаты RIQAS свидетельствуют об участии в авторитетной системе ВОК.



Программа Аммиак/Этанол+ (Ammonia/Ethanol Program+) С оценкой по цели

RQ9164 (2 мл)
2 Аналита
Ежемесячная, годовое участие

Аммиак

Этанол

Программа Антитела к рецептору ТТГ+ (Anti-TSH Receptor Program+) С оценкой по цели

RQ9174 (1 мл)
1 Аналит
Ежемесячная, годовое участие

Антитела к рецептору ТТГ (TRAb)

Программа Газы крови (Blood Gas Program) С оценкой по цели

RQ9134 (1.8 мл)
First registered instrument
11 аналитов
Ежемесячная, годовое участие

RQ9134/A (1.8 мл)
Subsequent instruments
11 аналитов

Бикарбонаты
Ca++
Cl-

CO2(Общий)
Глюкоза
Лактат

K+
Na+
pCO2

pH
pO2

Программа Мозговой натрийуретический пептид+ (BNP Program+) С оценкой по цели

RQ9165 (1 мл)
1 Аналит
Ежемесячная, годовое участие

Мозговой натрийуретический пептид (BNP)

Кардиологическая Программа (Cardiac Program) С оценкой по цели

RQ9127/a (1 мл)
2 Аналита (сна выбор из 7)
Образцы раз в 2 недели, 2 полугодовых цикла, годовое участие

RQ9127/b (1 мл)
Все 7 аналитов
Образцы раз в 2 недели, 2 полугодовых цикла, годовое участие

RQ9186 (1 мл)
Все 7 аналитов
Ежемесячная, годовое участие

Креатинкиназа Общая
КК-МВ (Активность)

КК-МВ (Масса)
Гомоцистеин

Миоглобин
Тропонин I

Тропонин T

Кардиологическая Расширенная Программа (Cardiac Plus Program) С оценкой по цели

RQ9190 (3 мл)
11 аналитов
Ежемесячная, годовое участие

Креатинкиназа Общая
КК-МВ (Активность)
КК-МВ (Масса)

Д-Димер
Дигоксин
Гомоцистеин

СРБ высокочувствительный
Миоглобин
NT proBNP

Тропонин I
Тропонин T

Программа Спинальная жидкость+ (Cerebrospinal Fluid Program+) С оценкой по цели

RQ9168 (3 мл)
7 аналитов
Ежемесячная, годовое участие

Альбумин
Хлориды

Глюкоза
IgG

Лактат
Белок (Общий)

Натрий

 Жидкие, готовые к использованию

 Лиофилизированные

ФИОЛЕТОВЫЙ = Доступны только в программе RQ9135/a

+ = Не аккредитованы

* = Пилотный цикл

ПРОГРАММЫ RIQAS

Программа Коагуляция (Coagulation Program) С оценкой по цели

RQ9135/a (1 мл) 5 анализов + 1 пилотный анализ (АЧТВ, ПТВ, ТВ, Фибриноген, Антитромбин III) Ежемесячная, годовое участие		RQ9135/b (1 мл) Все 16 анализов + 1 пилотный анализ	
АЧТВ Протромбиновое время (Включая МНО) Тромбиновое время Фибриноген Антитромбин III	Д-Димер* Фактор II Фактор V Фактор VII Фактор VIII	Фактор IX Фактор X Фактор XI Фактор XII Плазминоген	Протеин С Протеин S

Программа СО-оксиметрия+ (CO-Oximetry Program+)

RQ9177 (1.2 мл) Первый анализатор 7 анализов Ежемесячная, годовое участие		RQ9177/A (1.2 мл) Дополнительные анализаторы 7 анализов	
Карбоксигемоглобин (COHb / HbCO) Дезоксигемоглобин (HHb)	Метгемоглобин (MetHb) Содержание кислорода (O2CT)	Сатурация кислородом (sO2 / Vol O2) Оксигемоглобин (O-2Hb / HbO2)	Общий гемоглобин (tHb)

Программа Онкомаркер CYFRA 21-1+ (CYFRA 21-1 Program+)

RQ9175 (1 мл) 1 Анализ Ежемесячная, годовое участие	
CYFRA 21-1 (Цитокератин 19)	

Программа Цитокины+ (Cytokines Program+)

RQ9195 (1 мл) 1 Анализ + 11 pilots Ежемесячная, годовое участие			
Эпидермальный фактор роста (EGF)* Интерлейкин – 1 альфа (IL-1α)* Интерлейкин – 1 бета (IL-1β)* Интерлейкин – 2 (IL-2)*	Интерлейкин – 4 (IL-4)* Интерлейкин – 6 (IL-6) Интерлейкин – 8 (IL-8)* Интерлейкин – 10 (IL-10)*	Интерферон гамма (INF-γ)* Белок-хемоаттрактант моноцитов -1 (MCP-1)* Фактор некроза опухоли альфа (TNF-α)*	Сосудистый эндотелиальный фактор роста (VEGF)*

Программа СОЭ+ (ESR Programme+)

RQ9163 (4.5 мл) 1 Анализ 2 образца в квартал, годовое участие	
СОЭ (Скорость оседания эритроцитов)	

Программа Общая клиническая химия (General Clinical Chemistry Program) С оценкой по цели

RQ9112/a (5 мл) 10 анализов + 4 пилотных Образцы раз в 2 недели, 2 полугодовых цикла, годовое участие, данные по референсным методам		RQ9112/b (5 мл) 17 анализов + 4 пилотных		RQ9112/c (5 мл) Все 52 Анализа + 4 пилотных		RQ9128 (5мл) Все 52 Анализа + 4 пилотных Ежемесячная, годовое участие	
АПФ (ангиотензинпревращающий фермент) Кислая фосфатаза (Простатическая) Кислая фосфатаза (Общая) Альбумин Щелочная фосфатаза АЛТ (АЛАТ) Амилаза (Панкреатическая) Амилаза (Общая) АСТ (АСАТ) Бикарбонаты Желчные кислоты Билирубин (Прямой) Билирубин (Общий) Кальций Кальций, скорректированный	Кальций (Ионизированный) Хлориды Холестерин Холинэстераза Креатинкиназа (Общая) Медь Креатинин D-3-Гидроксибутират pCKF (расчетная скорость клубочковой фильтрации)* Фруктозамин ГГТ GLDH Глюкоза Гидроксибутиратдегидрогеназа	Холестерин ЛПВП Железо Лактат Лактатдегидрогеназа (LDH) Холестерин ЛПНП* Липаза Литий Магний Неэтерифицированные жирные кислоты (НЖК) Холестерин не ЛПВП* Осмоляльность Фосфор (Неорганический) Калий Белок (Общий)	ПСА Натрий ОЖСС Т3 (Свободный) Т3 (Общий) Т4 (Свободный) Т4 (Общий) Триглицериды ТТТ НЖСС Мочевина Мочевая кислота Цинк				



Жидкие, готовые к использованию



Лиофилизированные

ФИОЛЕТОВЫЙ – Доступны только в программе RQ9135/a

+ = Не аккредитованы

* = Пилотный цикл

Программа Гликозилированный гемоглобин (Glycated Haemoglobin Program (HbA1c))

С оценкой по цели

RQ9129 (0.5мл)
2 Аналита
Ежемесячная, годовое участие

Гемоглобин A1c

Общий гемоглобин

Программа Гематология (Haematology Program)

С оценкой по цели

RQ9118 (2 мл)
11 аналитов
Образцы раз в 2 недели, 2 полугодовых цикла, годовое участие

RQ9140 (2мл)
11 аналитов
Ежемесячная, годовое участие

Гематокрит (HCT)
Гемоглобин (Hb)
Среднее содержание гемоглобина в эритроците (MCH)

Средняя концентрация гемоглобина в эритроците (MCHC)
Средний объем эритроцита (MCV)
Средний объем тромбоцита (MPV)

Тромбоциты (PLT)
Тромбоцит (PCT)
Эритроциты (RBC)
Ширина распределения эритроцитов (RDW)

Лейкоциты (WBC)

Программа Биохимия мочи (Human Urine Program)

С оценкой по цели

RQ9115 (10 мл)
25 аналитов
Образцы раз в 2 недели, 2 полугодовых цикла, годовое участие

RQ9185 (10мл)
25 Аналита
Ежемесячная, годовое участие

ACR
Альбумин (Микроальбумин)
Амилаза
Кальций
Хлор
Медь
Кортизол

Креатинин
Дофамин
Эпинефрин
Глюкоза
Метанефрин
Норэпинефрин
Норметанефрин

Магний
Осмолальность
Оксалат
Фосфор (Неорганический)
Калий
Белок (Общий)
Натрий

Мочевина
Мочевая кислота
Ванилминдальная кислота (VMA)
5-гидроксииндолилуксусная кислота (5-HIAA)

Программа Иммунохимия (Immunoassay Program)

С оценкой по цели

RQ9125/a (5 мл)
4 Аналита + 2 пилотных

RQ9125/b (5 мл)
13 Аналита + 2 пилотных

RQ9125/c (5 мл)
Все 49 Аналита + 2 пилотных

RQ9130 (5 мл)
Все 49 Аналита + 2 пилотных
Ежемесячная, годовое участие
RQ9130)

Образцы раз в 2 недели, 2 полугодовых цикла, годовое участие (RQ9125/a, RQ9125/b, RQ9125/c)

АКТГ
Альфа-фетопротеин (АФП)
Альдостерон
Амикацин
Андростендион
β-2-Микроглобулин
CA125
CA15-3
CA19-9
Карбамазепин
РЭА
Кортизол
С-пептид

ДГЭА-сульфат
ДГЭА неконъюгированный
Дигоксин
Ферритин
Фолат
ФСГ
Гентамицин
Гормон роста
ХГЧ
IgE
Инсулин
Лютеонизирующий гормон
Эстрадиол

17-ОН-Прогестерон
Парацетамол
Фенобарбитал
Фенитоин
Прогестерон
Пролактин
ПСА (Свободный)
ПСА (Общий)
Паратериоидный гормон (PTH)
Салицилаты
ГСПГ
ТЗ (Свободный)
ТЗ (Общий)

T4 (Свободный)
T4 (Общий)
Testosterone (Свободный)*
Testosterone (Общий)
Теофиллин
Тиреоглобулин
ТТГ
Вальпроевая кислота
Ванкомицин
Витамин B12
1,25-(ОН)2-Витамин D*
25-ОН-Витамин D

Программа Специальная иммунохимия 1 (Immunoassay Specialty 1 Program)

С оценкой по цели

RQ9141 (2 мл)
9 аналитов + 1 пилотный
Ежемесячная, годовое участие

1,25-(ОН)2-Витамин D*
25-ОН-Витамин D
С-пептид

Анти-Тиреоглобулин
Анти-Тиреопероксидаза
Инсулиноподобный фактор роста-1

Остеокальцин
Прокальцитонин
Паратиреоидный гормон

Инсулин

Программа Специальная иммунохимия 2 (Immunoassay Specialty 2 Program)

С оценкой по цели

RQ9142 (1 мл)
5 аналитов
Ежемесячная, годовое участие

Кальцитонин
Гастрин

Прокальцитонин
Ренин (Активность в плазме)

Ренин (Прямое определение концентрации)



Жидкие, готовые к использованию



Лиофилизированные

ФИОЛЕТОВЫЙ – Доступны только в программе RQ9135/a

+ = Не аккредитованы

* = Пилотный цикл

ПРОГРАММЫ RIQAS

Программа Иммунодепрессанты+ (Immunosuppressant Program+)

RQ9159 (2 мл)

4 Аналита

Ежемесячная, годовое участие, данные референсных методов

Циклоспорин

Эверолимус

Сиролимус

Такролимус

Программа Липиды (Lipid Program) *С оценкой по цели*

RQ9126/a (3 мл)

3 Аналита (на выбор из 7)

RQ9126/b (3 мл)

Все 7 Аналита

Образцы раз в 2 недели, 2 полугодов цикла, годовое участие

Аполипопротеин A1

Аполипопротеин B

Холестерин (Общий)

Холестерин ЛПВП

Холестерин ЛПНП

Липопротеин (a)

Триглицериды

Программа Перинатальный скрининг (Maternal Screening Program) *С оценкой по цели*

RQ9137 (1 мл)

6 анализов

Ежемесячная, годовое участие

Альфа-фетопроtein

Свободный β -ХГЧ

ХГЧ (Общий)

Ингибин А

PAPP-A

Эстриол неконъюгированный

Программа Неонатальный билирубин+ (Neonatal Bilirubin Program+)

RQ9191 (3 мл)

2 Аналита

Ежемесячная, годовое участие

Билирубин Прямой

Билирубин Общий

Программа Серология Анти-SARS-CoV-2+ (Serology (Anti-SARS-CoV-2) Program+)

RQ9193 (0.5 мл)

3 Аналита

Ежемесячная, годовое участие

IgG

IgM

Суммарные антитела

Программа Серология Вирус Эпштейна-Барр+ (Serology (EBV) Program+)

RQ9153 (1 мл)

3 Аналита

Ежемесячная, годовое участие, количественный и качественные результаты

Anti-EBV VCA IgG

Anti-EBNA IgG

Anti-EBV VCA IgM

Программа Серология ВИЧ+ (Serology (HIV-Hepatitis) Program+)

RQ9151 (1.8 мл)

16 анализов

Ежемесячная, годовое участие, количественный и качественные результаты

Антитела к цитомегаловирусу

(Суммарные)

Антитела к вирусу гепатита A IgM*

Антитела к вирусу гепатита A

(Суммарные)*

Антитела к ядерному антигену

вируса гепатита B (Суммарные)

Антитела к ядерному антигену

вируса гепатита B IgM*

Антитела к e-антигену вируса гепатита

B (Суммарные)*

Антитела к поверхностному антигену

вируса гепатита B (Суммарные)*

Антитела к вирусу гепатита C

Антитела к ВИЧ-1

Антитела к ВИЧ-2

Антитела к ВИЧ (Комбинированные)

Антитела к Т-лимфотропному вирусу

человека I

Антитела к Т-лимфотропному вирусу

человека II

Антитела к Т-лимфотропному вирусу

человека (Комбинированные)

Поверхностный антиген вируса

гепатита B (HBsAg)

Антиген ВИЧ P24*



= Жидкие, готовые к использованию



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Программа Серология Сифилис+ (Serology (Syphilis) Program+)

RQ9154 (1 мл)

1 Анализ

Ежемесячная, годовое участие, количественный и качественные результаты

Сифилис (Доступные методы включают: иммунохимический анализ, RPR, VDRL и TPHA)

Программа Серология ToRCH+ (Serology (ToRCH) Program+)

RQ9152 (1 мл)

15 анализов

Ежемесячная, годовое участие, количественный и качественные результаты

Антитела к цитомегаловирусу IgG

Антитела к цитомегаловирусу IgM

Антитела к вирусу простого герпеса 1 IgG

Антитела к вирусу простого герпеса 1 IgM

Антитела к вирусу простого герпеса 2 IgG

Антитела к вирусу простого герпеса 2 IgM

Антитела к вирусу простого герпеса 1/2 IgG

Антитела к вирусу простого герпеса 1/2 IgM

Антитела к вирусу кори IgG*

Антитела к вирусу свинки IgG*

Антитела к вирусу краснухи IgG

Антитела к вирусу краснухи IgM

Антитела к вирусу токсоплазмы IgG

Антитела к вирусу токсоплазмы IgM

Антитела к вирусу ветряной оспы IgG*

Программа Сывороточные индексы+ (Serum Indices Program+)

RQ9194 (1 мл)

Оценка 3 индексов

25 анализов

Образцы дважды в месяц (9 образцов в поставке), 2 поставки за цикл

RQ9194/A (1 мл)

Оценка индексов (Качественно и полу-количественно)

Гемоллиз

Иктеричность

Липемичность

Определяемые аналиты (Количественно)

Щелочная фосфатаза

АЛТ (АЛТ)

АСТ (АСТ)

Билирубин (Прямой)

Билирубин (Общий)

Кальций

Хлориды

Холестерин

НАС-активированная креатинкиназа

Креатинин

ГТТ

Глюкоза

Холестерин ЛПВП

Железо

Лактат

Холестерин ЛПНП

Липаза

Магний

Фосфор

Калий

Белок (Общий)

Натрий

Триглицериды

Мочевина

Мочевая кислота

Программа Специфические белки (Specific Proteins Program) С оценкой по цели

RQ9114 (3 мл)

26 анализов

Образцы раз в 2 недели, 2 полугодичных цикла, годовое участие

RQ9187 (1мл)

26 анализов

Ежемесячная, годовое участие

Альфа-фетопrotein

Альбумин

α-1-кислый гликопротеин

α-1-антитрипсин

α-2-макроглобулин

Анти-стрептолизин О

Антипротромбин III

β-2-микроглобулин

Церулоплазмин

Комплемент C3

Комплемент C4

С-реактивный белок

Ферритин

Гаптоглобин

IgA

IgE

IgG

IgM

Каппа легкая цепь (Свободная)

Каппа легкая цепь (Общая)

Лямбда легкая цепь (Свободная)

Лямбда легкая цепь (Общая)

Преальбумин (Трансферин)

Ретинол-связывающий белок

Ревматоидный фактор

Трансферин

Программа Исследование пота+ (Sweat Testing Program+)

RQ9173 (2 мл)

2 анализов

Ежемесячная, годовое участие

Хлориды

Электропроводность

Программа Лекарственный мониторинг (Therapeutic Drugs Program) С оценкой по цели

RQ9111 (5 мл)

18 анализов

Образцы раз в 2 недели, 2 полугодичных цикла, годовое участие, Взвешенные значения

Амикацин

Кофеин

Карbamазепин

Циклоспорин

Дигоксин

Этосуксимид

Гентамицин

Литий

Метотрексат

Парацетамол (ацетаминофен)

Фенобарбитал

Фенитоин

Примидон

Салициловая кислота

Теofilлин

Тобрамицин

Вальпроевая кислота

Ванкомицин



Жидкие, готовые к использованию



Лиофилизированные

ФИОЛЕТОВЫЙ – Доступны только в программе RQ9135/а

* – Не аккредитованы

* – Пилотный цикл

ПРОГРАММЫ RIQAS

Программа Микроэлементы в цельной крови+ (Trace Elements In Blood Program+)

RQ9172 (3 мл)
7 аналитов
Ежемесячная, годовое участие

Медь	Свинец	Марганец	Цинк
Йод	Магний	Селен	

Программа Микроэлементы в сыворотке+ (Trace Elements In Serum Program+)

RQ9170 (3 мл)
10 аналитов
Ежемесячная, годовое участие

Алюминий	Медь	Марганец	Цинк
Хром	Йод	Никель	
Кобальт	Свинец	Селен	

Программа Микроэлементы в моче+ (Trace Elements In Urine Program+)

RQ9171 (3 мл)
11 аналитов
Ежемесячная, годовое участие

Кадмий	Медь	Магний	Никель
Хром	Йод	Марганец	Таллий
Кобальт	Свинец	Молибден	

Программа Общий анализ мочи (Urinalysis Program) With scoring

RQ9138 (12 мл)
14 аналитов
Образцы каждые 2 месяца, годовое участие

Альбумин	Галактоза	Лейкоциты	Удельный вес
Билирубин	Глюкоза	Нитриты	Уробилиноген
Кровь	ХГЧ	pH	
Креатинин	Кетоны	Белок (Общий)	

Программа Токсикология мочи+ (Urine Toxicology Program+)

RQ9139 (5 мл)
20 аналитов
Ежемесячная, годовое участие

Бензолеконин	d-метамфетамин	ЛСД	Фенциклидин
Бупренорфин	2-Этилен-1,5-диметил-3,3-дифенилпирролин (EDDP)	МДМА	Фенобарбитал
Каннабиноиды (THC)	Этанол	Метадон	Секобарбитал
Котинин	Свободный морфин	Нортритилин	
Креатинин	Лоразепам	Нортпроксифен	
d-амфетамин		Оксазепам	



= Жидкие, готовые к использованию



= Лифофилизованные

ФИОЛЕТОВЫЙ = Доступны только в программе RQ9135/2

+ = Не аккредитованы

* = Пилотный цикл

Несмотря на то, что предпринимаются все усилия, чтобы обеспечить точность и актуальность информации в наших каталогах, некоторые данные могут быть изменены, пожалуйста, свяжитесь с RIQAS для получения актуальной информации.

RIQAS 



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LT208RUS APR22

ENGLISH

GLYCATED HAEMOGLOBIN (HbA1c) PROGRAMME: RQ9129

CONFIRMATION OF KIT CHARACTERISTICS AND RECEIPT DATE

Please confirm that the correct number of samples are present and that your samples have the appearance as indicated in the CHARACTERISTICS section below. Please confirm that none of the vials are broken and notify your local Randox representative immediately if there are any discrepancies. Finally, please log on to www.riqas.net to confirm the exact date on which you received this kit.

CHARACTERISTICS

The pack contains 6 vials of lyophilised 0.5 ml samples. The vials are labelled with the sample number.

PREPARATION/STORAGE/STABILITY OF SAMPLES

The samples are sealed under vacuum. Open the vial very carefully, avoiding any loss of material and reconstitute with an accurately measured 0.5ml volume of freshly distilled water at +20°C to +25°C. Replace the sample bottle cap, swirl the bottle several times and leave to stand at room temperature for 15 minutes. After 15 minutes, coat all surfaces of the bottle by rotating and inverting the bottle. Continue mixing until the solution is homogeneous and all lyophilised material is reconstituted. Do not shake the vial. The reconstituted sample should be analysed within 2 days. Do not freeze the reconstituted samples. The samples should be stored at 2 to 8°C when not in use.

NB. The reconstituted samples should be treated the same as patient samples. Depending on the method of analysis, they may require pre-treatment (either on the analyser, or manually) in order to assay for HbA1c.

SAFETY

Potentially Biohazardous Material. The samples contain human blood. Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

For **IN VITRO** use only, do not pipette by mouth, exercise the normal precautions required for handling laboratory reagents.

*** IMPORTANT NOTE:** Results must arrive at **RIQAS** by **17:00 hrs GMT** on the **FINAL DATE**. If the **RECOMMENDED ANALYSIS DATE** gives insufficient time, we suggest that the sample is analysed earlier to ensure you meet the deadline. Late results will not be accepted after the final date for the next sample.

GLYCATED HAEMOGLOBIN (HbA1c) PROGRAMME / PROGRAMME HEMOGLOBINE GLYQUEE (HbA1c) /
PROGRAMMA EMOGLOBINA GLICATA (HbA1c) / PROGRAMA DE HEMOGLOBINA GLICOSILADA (HbA1c) /
HEMOGLOBINA GLICADA (HbA1c) PROGRAMA / GLYCATED HAEMOGLOBIN (HbA1c) PROGRAM /
PROGRAM DO OZNACZANIA HEMOGLOBINY GLIKOWANEJ (HbA1c) / CHƯƠNG TRÌNH NGOẠI KIỂM (HbA1c) /
GLIKOLIZE HEMOGLOBIN (HbA1c) PROGRAMI

RETURN OF RESULTS / DATES de RETOUR / INVIO DEI RISULTATI / ENVIO DE RESULTADOS
PLAN FOR INSENDELSE AF / ZWROTU WYNIKÓW / GŪI TRẢ KẾT QUẢ / SONUÇ GÖNDERİM TARİHLERİ / ODOŚLANIE WYŚLEDKÓV

CYCLE 19A / CICLO 19A / RESULTATER 19A / CYKL 19A / CHU KỲ 19A / DÖNEM 19A / CYKLUS 19A

SAMPLE NO / ECHANTILLON NO, /
N. CAMPIONE / N° DE MUESTRA /
AMOSTRA N°. / PRŮVENR. /
PROV NR. / MẪU SỐ
ÖRNEK NO / Č.VZORKY

RECOMMENDED ANALYSIS DATE / DATE RECOMMANDE POUR L' ANALYSE /
DATA DI ANALISI RACCOMANDATA / FECHA DE ANALISIS RECOMENDADA /
DATA RECOMENDADA PARA ANÁLISE / ANBEFALET ANALYSEDATO /
ZALECANA DATA WYKONANIA OZNACZENIA / NGÀY KHUYẾN CÁO PHÂN TÍCH
ÖNERİLEN ANALİZ TARİHİ / ODPORÚČANÝ DATUM ANALÝZY

* FINAL DATE / *DATE LIMITE /
* DATA FINALE / *FECHA FINAL /
* DATA FINAL / * SLUTDATO / SIDSTE DATO
* SLUTDATUM / * HẠN CUỐI GŪI TRẢ KẾT QUẢ
*SON SONUÇ GÖNDERİM TARİHİ /
*FINÁLNY DATUM

1	15.01.24	22.01.24
2	12.02.24	19.02.24
3	11.03.24	18.03.24
4	08.04.24	15.04.24
5	13.05.24	20.05.24
6	10.06.24	17.06.24

FRANÇAIS

PROGRAMME HEMOGLOBINE GLYQUEE (HbA1c): RQ9129

CONFIRMATION DES CARACTERISTIQUES DU KIT ET DE LA DATE DE RECEPTION:

Veuillez vérifier que l'ensemble des échantillons soient présents dans le coffret et que leur apparence est conforme comme indiqué dans la section ci-dessous. De plus assurez-vous qu'aucun des flacons ne soient brisés et en informer immédiatement votre représentant Randox si cela est le cas. Enfin, il est nécessaire de se connecter à www.riqas.net pour confirmer la date exacte à laquelle vous avez reçu ce kit.

CARACTÉRISTIQUES:

Ce coffret contient 6 sérums lyophilisés en flacons de 0.5 ml, étiquetés 1 à 6.

PREPARATION/STOCKAGE/STABILITE DES ECHANTILLONS

Les flacons sont scellés sous vide. Ouvrir avec précaution le flacon en évitant toute perte de matériel et reconstituer avec 0.5 ml d'eau distillée à une température comprise entre +20 et +25 °C. Remplacer le bouchon, agiter délicatement le flacon plusieurs fois et laisser reposer 15 minutes à température ambiante. Après 15 minutes, procéder à plusieurs retournements afin d'obtenir une solution homogène et s'assurer que tout le matériel lyophilisé soit dissout. Ne pas agiter le flacon. Une fois le flacon reconstitué, l'analyse des paramètres doit être réalisée dans les deux jours. Ne pas congeler les échantillons reconstitués. Les échantillons doivent être conservés entre 2-8 °C lorsqu'ils ne sont pas utilisés.

NB. Le contrôle reconstitué doit être traité comme un échantillon patient. Le pré-traitement dépend de votre méthode d'analyse, se référer à votre protocole.

SÉCURITÉ

Produit à risque biologique. Les échantillons contiennent du sang humain. Les donneurs du matériel source, dont ce produit a été dérivé, ont été testés pour la présence d'anticorps de l'Human Immunodeficiency Virus (HIV 1, HIV 2), l'antigène de surface de l'Hépatite B (HbsAg), et d'anticorps du virus de l'Hépatite C (HCV) et ont été trouvés NÉGATIFS. Ces tests ont été effectués par des méthodes approuvées par la FDA (US Food and Drug Administration). Cependant, aucun test ne pouvant apporter une garantie totale sur le caractère non infectieux de ces produits, il est recommandé de les manipuler et de les détruire selon les précautions requises pour tout matériel à risque biologique.

A usage **IN VITRO** exclusivement. Ne pas pipeter avec la bouche. Appliquer les précautions d'usage recommandées pour les manipulations des réactifs en laboratoire.

*** NOTE IMPORTANTE:** Les résultats **RIQAS** doivent parvenir au Département **RIQAS** au plus tard le lundi midi selon la **DATE FINALE**. Nous vous recommandons d'analyser les échantillons quelques jours avant la date finale. Les résultats en retard ne seront pas acceptés après la date finale de l'échantillon suivant. Vous pouvez envoyer vos résultats via Riqasnet ou par e.mail à l'adresse suivante: mail@riqas.com.

ITALIANO

PROGRAMMA EMOGLOBINA GLICATA (HbA1c): RQ9129

CONFERMA DELLE CARATTERISTICHE DEL KIT E DELLA DATA DI RICEZIONE

Si prega di confermare che sia presente il numero corretto di campioni e che i vostri campioni siano come indicato nella sezione CARATTERISTICHE qui sotto. Confermare che nessuna fiala sia rotta ed informare immediatamente il rappresentante Randox locale se ci fossero delle discrepanze. Infine, si prega di accedere al sito www.riqas.net per confermare la data esatta in cui si è ricevuto questo kit.

CARATTERISTICHE

La confezione contiene 6 fiale da 0.5 ml di campioni liofilizzati. Le fiale sono etichettate con il numero del campione.

PREPARAZIONE/CONSERVAZIONE/ STABILITA' DEI CAMPIONI

I campioni sono stati sigillati sotto vuoto. Aprire la fiala con estrema cautela, evitando qualsiasi fuoriuscita di materiale e ricostituire con un volume accuratamente misurato di 0.5ml di acqua appena distillata a +20 °C - +25 °C. Richiudere avvitando il tappo della confezione, roteare il flacone più volte e lasciare riposare a temperatura ambiente per 15 minuti, passati i quali, ruotando e mettendo sottosopra il flacone, fare in modo che le superfici interne ne siano del tutto rivestite. Continuare a miscelare sino a che la soluzione appaia omogenea e tutto il materiale liofilizzato sia ricostituito. Non agitare la fiala. Analizzare i vostri campioni entro 2 giorni dalla ricostituzione. Non congelare i campioni ricostituiti. I campioni, se non utilizzati, devono essere conservati a 2 - 8 °C.

NB. I campioni ricostituiti dovrebbero essere trattati allo stesso modo di quelli dei pazienti. In base al metodo analitico, potrebbe essere richiesto un pre-trattamento (o sull' analizzatore o manualmente) per poter effettuare la misurazione dell' HbA1c.

SICUREZZA

Materiale potenzialmente pericoloso. I campioni contengono sangue umano. Il materiale di origine umana dal quale deriva il prodotto è stato controllato, relativamente al donatore, per l'eventuale presenza degli anticorpi da Virus da Immunodeficienza acquisita (HIV 1, HIV 2) , antigene di superficie dell'Epatite B (HbsAg) ed anticorpi da virus dell'Epatite C (HCV) e trovato NON REATTIVO. Nell'esecuzione di tali prove sono stati utilizzati metodi approvati dall'FDA. Comunque, dal momento che nessun metodo può offrire la totale sicurezza dell'assenza di agenti infettivi, tale materiale ed i campioni dei pazienti devono essere maneggiati come fossero in grado di trasmettere malattie infettive e quindi smaltiti di conseguenza.

Per l'esclusivo uso **IN-VITRO**, non pipettare con la bocca e mettere in atto le normali precauzioni richieste nel maneggiare reagenti di laboratorio.

*** NOTA IMPORTANTE:** I risultati devono arrivare a **RIQAS** entro le **17:00 GMT** dell' **ULTIMA DATA**. Se la **DATA RACCOMANDATA PER L'ANALISI** non fornisce tempo a sufficienza, suggeriamo di analizzare il campione prima per essere certi di rispettare la scadenza. Risultati in ritardo non saranno accettati dopo l'ultima data del campione successivo.

PROGRAMA DE HEMOGLOBINA GLICOSILADA (HbA1c): RQ9129

CONFIRMACION DE LAS CARACTERISTICAS DEL KIT Y LA FECHA DE RECEPCION.

Por favor, Asegúrese de que ha recibido el número correcto de muestras y que estas cumplen con la presentación indicada en la sección "CARACTERISTICAS" que encontrará a continuación. Por favor, confirme que ninguna de las muestras ha resultado dañada y contacte a su Representante local de Randox inmediatamente en el caso de que hubiese alguna discrepancia. Por último, Acceda a www.riqas.net para confirmar la fecha exacta en la que recibió el kit.

CARACTERÍSTICAS

El paquete contiene 6 frascos de muestras liofilizadas de 0.5 ml. Las etiquetas de los frascos indican el número de muestra

PREPARACIÓN/ ALMACENAMIENTO/ ESTABILIDAD DE LAS MUESTRAS

Las muestras están selladas al vacío. Abrir el frasco con mucho cuidado, para evitar cualquier pérdida de material y reconstituir con una medida muy precisa de 0.5 ml de agua destilada recientemente y conservada entre +20°C y +25°C. Reemplace el tapón de la botella, reestandarícela varias veces a temperatura ambiente y déjela reposar durante 15 minutos. Transcurridos los 15 minutos, recubra todas las superficies interiores de la botella rotándola e invirtiéndola. Continúe mezclándola hasta que la solución esté homogénea y se haya reconstituido todo el material liofilizado. No agite el vial. Por favor, analice las muestras dentro de los 2 días posteriores a su reconstitución. No congele las muestras reconstituidas. Las muestras deben refrigerarse a 2-8 °C cuando no estén en uso.

Nota. Las muestras reconstituidas deberían ser tratadas como las muestras de pacientes en el método de análisis pudiese requerir pre-tratamiento (en el autoanalizador, o manual) para informar sobre el porcentaje de HbA1c.

SEGURIDAD

Material potencialmente biopeligroso. Estas muestras contienen sangre humana. EL material Humano del que se deriva este producto, ha sido examinado a nivel de donante en cuanto a su reacción frente a anticuerpos del Virus de la Inmunodeficiencia Humana (HIV 1, HIV 2), frente al Antígeno de Superficie de la Hepatitis B (HbsAg), y a Anticuerpos frente al Virus de la Hepatitis C (HCV) y se han encontrado NO-REACTIVOS., por métodos de ensayo aprobados por la FDA. Sin embargo, dado que ningún método de análisis puede ofrecer completa certeza sobre la ausencia de agentes infecciosos, este material y todas las muestras de pacientes, deberían ser tratadas como potencialmente infecciosas y desechados de forma consecuente.

Par el uso exclusivo de **IN VITRO**, no pipetear con la boca. Ejercite las precauciones normales requeridas para tratar reactivos de laboratorio.

*** NOTA IMPORTANTE:** Los resultados deben arribar a **RIQAS** a las **17:00 horas GMT** en la **FECHA FINAL**. Si la **FECHA RECOMENDADA PARA ANALISIS** dada es insuficiente, le sugerimos que analice la muestra antes para asegurarse que la tenga lista en la fecha final. Los resultados tardíos no serán aceptados después de la fecha final de la siguiente muestra.

PORTUGUÊS

HEMOGLOBINA GLICADA (HbA1c) PROGRAMA: RQ9129

CONFIRMAÇÃO DAS CARACTERÍSTICAS DO KIT E DATA DE RECEPÇÃO

Agradecemos-lhe que confirme que recebeu o número correcto de amostras e que estas têm o aspecto descrito na secção CARACTERÍSTICAS deste documento. Verifique também, se nenhum dos frascos está partido e notifique o seu representante local da Randox caso encontre alguma discrepância. Finalmente, acceda ao www.riqas.net para confirmar a data exacta em que recebeu este kit.

CARACTERÍSTICAS

A embalagem contém 6 frascos de 0.5 ml de amostras liofilizadas. Os frascos encontram-se rotulados com o número de amostra.

PREPARAÇÃO/CONSERVAÇÃO/ESTABILIDADE DAS AMOSTRAS

As amostras são seladas sob vácuo. Abrir o frasco cuidadosamente, evitando perda de material e reconstituir com o volume preciso de 0.5 ml de água destilada de +20°C a +25°C. Colocar a tampa no frasco, rodar suavemente o frasco várias vezes e deixar em repouso à temperatura ambiente por 15 minutos. Depois de 15 minutos, molhar a superfície do frasco rodando-o e invertendo-o. Continuar a misturar até que a solução esteja homogénea e todo o material liofilizado esteja reconstituído. Não agitar o frasco. Por favor analise as suas amostras dentro de 2 dias após reconstituição. Não congelar as amostras reconstituídas. As amostras devem ser conservadas de 2-8 °C quando não estão a ser usadas.

NB. As amostras reconstituídas devem ser tratadas da mesma forma que as amostras de doentes. Dependendo de método de análise, podem requerer pré-tratamento (tanto no analisador como manualmente) para ensaiar a HbA1c.

SEGURANÇA

Material potencialmente nocivo biologicamente. As amostras contém sangue humano. A fonte humana de onde este produto foi obtido foi testada ao nível do dador quanto ao anticorpo do Vírus da Imunodeficiência Humana (HIV 1, HIV 2), Antígeno de superfície Hepatite B (HbsAg), e anticorpo do Vírus da Hepatite C (HCV) e detectou-se ser NÃO -REACTIVO Foram usados métodos aprovados pela FDA para conduzir estes testes. No entanto, uma vez que nenhum método pode oferecer garantia total quanto a ausência de agentes infecciosos, este material, bem como as amostras de doentes, devem ser manuseados como sendo capazes de transmitir doenças infecciosas.

Para utilização exclusiva **IN VITRO**, não pipetar com a boca, respeitar as precauções normais necessárias para manuseamento de reagentes de laboratório.

*** NOTA IMPORTANTE:** Os resultados devem chegar ao **RIQAS** na **DATA FINAL** até às **17 horas, GMT**. Se a **DATA RECOMENDADA PARA ANÁLISE** não permitir tempo suficiente para o envio, sugere-se que a amostra seja ensaiada antecipadamente, de forma a garantir o cumprimento do prazo final. Os resultados em atraso não serão aceites após a data final da amostra seguinte.

DANSK

GLYCATED HAEMOGLOBIN (HbA1c) PROGRAM: RQ9129

BEKRÆFTELSE PÅ KIT KARAKTERISTIKA OG MODTAGELSESDATO

Du bedes kontrollere at det korrekte antal af prøver er tilstede i kittet og at prøverne ser ud som beskrevet i KARAKTERISTIKA-afsnittet nedenfor. Kontroller venligst at alle flasker er intakte og kontakt straks din lokale Randox repræsentant, hvis der er uoverensstemmelser. Endelig, så bedes du logge på www.riqas.net og bekræfte datoen, hvor du modtog dette kit.

KARAKTERISTIKA

Pakningen indeholder 6 rør med 0.5 ml frysetørrede prøver. Rørene er mærket med prøvenummer.

FORBEREDELSE/OPBEVARING/STABILITET AF PRØVER

Prøverne er forsegled under vacuum. Røret åbnes meget forsigtigt for at undgå spild af materialet, og indholdet opløses med præcis 0.5 ml redestilleret vand ved +20°C til +25°C. Sæt flaskelåget på igen, mix flasken flere gange på whirlymixer og lad stå ved rumtemperatur i 15 minutter. Efter 15 minutter, skab belægning på alle overflader i flasken ved at rotere og vende flasken rundt. Fortsæt med at mixe indtil opløsningen er homogen og alt lyofiliseret materiale er rekonstitueret. Flasken må ikke rystes. Jeres prøver bør analyseres indenfor 2 dage efter genopløsning. Rekonstituerede prøver må ikke fryses. As amostras devem ser conservadas de -2-8 °C quando não estão a ser usadas.

NB. De rekonstituerede prøver bør behandles på samme måde som patientprøver. Afhængigt af analysemetoden kan de behøve for-behandling (enten på analysen, eller manuelt) for at kunne testes for HbA1c.

SIKKERHED

Potentielt Biohazard Materiale. Prøverne indeholder humant blod. Det humane kildemateriale, som dette product er udviklet fra, er blevet testet på donor niveau for Human Immunodeficiency Virus (HIV 1, HIV 2) antistof, Hepatitis B overflade Antigen (HbsAg) og Hepatitis C Virus (HCV) antistof og fundet at være IKKE-REAKTIVT. FDA godkendte metoder er blevet anvendt til at udføre disse tests. Bemærk dog, at siden ingen metode kan give fuldstændig sikkerhed for fraværet af infektiøse agenter, så bør dette materiale og alle patientprøver håndteres som om de er smittefarlige og bortkastet korrekt efter endt brug.

Til **IN VITRO** brug, undgå mund-pipettering, udvis normale forholdsregler for håndtering af laboratoriereagenser.

*** VIGTIG NOTE:** Resultaterne skal være **RIQAS** i hænde senest kl. **17.00 GMT** på datoen for **SENESTE FRIST**. Hvis den **ANBEFALEDE ANALYSEDATO** ikke muliggør overholdelsen af dette, anbefaler vi at prøven analyseres før denne dato for at sikre at deadline overholdes. Forsinkede resultater vil ikke blive accepteret efter slutdatoen for den næste prøve.

POLSKI

PROGRAM DO OZNACZANIA HEMOGLOBINY GLIKOWANEJ (HbA1c) : RQ9129

POTWIERDZENIE CHARAKTERYSTYKI ZESTAWU I DATY ODBIORU

Prosimy o potwierdzenie, że zestaw zawiera odpowiednią ilość próbek i Państwa próbki wyglądają tak, jak w podanej poniżej CHARAKTERYSTYCE.

Prosimy o potwierdzenie, że żadna z próbek nie jest zbita, a jeśli są jakiegokolwiek niezgodności prosimy o niezwłoczne zgłoszenie tego lokalnemu przedstawicielowi.

Następnie prosimy o zalogowanie się na www.riqas.net w celu potwierdzenia dokładnej daty otrzymania zestawu.

CHARAKTERYSTYKA

Opakowanie zawiera 6 fiolek próbek liofilizowanych po 0.5 ml. Fiolki są oznakowane numerem próbki.

PRZYGOTOWANIE/PRZECZYSZCZANIE/STABILNOŚĆ PRÓBEK

Próbki są zamknięte metodą próżniową. Otworzyć fiolkę bardzo ostrożnie, unikając utraty materiału i rekonstruować w dokładnie odmierzonym objętości 0.5 ml świeżo destylowanej wody w temperaturze od +20 do +25°C. Zamknąć fiolkę korkiem, zamieszać kilka razy i pozostawić na 15 minut w temperaturze pokojowej. Po 15 minutach pokryć wszystkie powierzchnie butelki poprzez obracanie i odwracanie butelki. Kontynuować mieszanie dopóki roztwór nie będzie jednorodny i całkowicie rozpuszczony cały materiał liofilizowany. Nie wstrząsać fiolką. Prosimy wykonać oznaczenie nie później niż w ciągu dwóch dni od przygotowania materiału. Nie zamrażać zrekonstruowanej próbki. Próbkę, kiedy nie są w użyciu powinny być przechowywane w temperaturze 2-8 °C.

UWAGA. Zrekonstruowane próbki zaleca się traktować tak samo jak materiał pobrany od pacjentów. W zależności od metody oznaczania próbek, może być wymagane wstępne przygotowanie próbki (przy użyciu analizatora bądź manualnie) w celu oznaczenia HbA1c.

BEZPIECZEŃSTWO

Materiał potencjalnie szkodliwy biologicznie. Próbki zawierają krew ludzką. Materiały pochodzenia ludzkiego, z których pochodzi ten produkt, były badane pod względem obecności przeciwciał przeciwko wirusowi ludzkiego niedoboru odporności (HIV 1, HIV 2), antygenu powierzchniowego wirusa zapalenia wątroby typu B (Hbs Ag) oraz przeciwciał przeciwko wirusowi zapalenia wątroby typu (HCV) i zostały uznane za NIE-REAKTYWNE. W celu przeprowadzenia tych testów zastosowano metody zatwierdzone przez FDA. Ponieważ żadna metoda nie daje całkowitej pewności nieobecności czynników zakaźnych, dlatego ten materiał i wszystkie próbki od pacjentów powinny być traktowane jako potencjalne źródło chorób zakaźnych i usuwane w odpowiedni sposób.

Tylko do **IN VITRO**, nie pipetować ustami, zachować ostrożność wymaganą przy używaniu odczynników laboratoryjnych.

*** UWAGA:** Wyniki muszą dotrzeć do **RIQAS** do godziny **17:00 czasu GMT** w dniu **DATY FINALNEJ**. Jeżeli **ZAŁECANA DATA OZNACZENIA** jest zbyt późna, sugeruje się przeprowadzenie wcześniejszej analizy, aby uzyskać czas na przesłanie wyników. Spóźnione wyniki przesłane po dacie finalnej następnej próbki nie zostaną przyjęte.

XÁC NHẬN VỀ NHỮNG ĐẶC TÍNH MẪU VÀ NGÀY NHẬN

Xin vui lòng xác nhận rằng bạn đã nhận đúng và đầy đủ số lượng mẫu, những mẫu đó được mô tả như phần "ĐẶC TÍNH" dưới đây. Xin vui lòng xác nhận không có lọ mẫu nào bị vỡ hoặc hư hỏng và thông báo ngay cho đại diện của hãng Randox tại địa phương của bạn nếu có sai lệch. Sau cùng, xin vui lòng đăng nhập vào www.riqas.net để xác nhận thời gian chính xác mà bạn đã nhận bộ mẫu này.

ĐẶC ĐIỂM

1 hộp bao gồm 6 lọ mẫu dạng đông khô, mỗi lọ 0.5 ml (6 x 0.5 ml) được đánh số thứ tự từ 1-6 theo số thứ tự mẫu phân tích

CHUẨN BỊ/BẢO QUẢN/ĐỘ BỀN CỦA MẪU

Lọ mẫu được đóng nắp chần không. Mở nắp lọ cẩn thận tránh làm thất thoát, pha loãng với chính xác 0.5ml nước cất hai lần ở **+20°C - +25°C**. Đậy nắp cao su và lắc nhẹ nhàng sau đó để mẫu yên ở nhiệt độ phòng trong 15 phút. Sau 15 phút, đảo đều lọ mẫu để mẫu hòa tan hoàn toàn tạo dung dịch đồng nhất. Chú ý không được lắc mạnh. Khuyến cáo phân tích mẫu trong vòng 2 ngày sau khi hoàn nguyên.. Không được đông lạnh mẫu đã hoàn nguyên. Những mẫu này nên được bảo quản ở nhiệt độ 2-8 °C khi chưa sử dụng

Chú ý: Mẫu phân tích sau khi hoàn nguyên được xử lý giống như mẫu bệnh nhân. Tùy thuộc vào phương pháp phân tích, mẫu có thể phải tiền xử lý (ly giải hồng cầu) trước khi phân tích HbA1c

ĐỘ AN TOÀN

Có khả năng độc hại về sinh học. Mẫu chứa thành phần từ máu người và đều được kiểm tra âm tính với HIV-1, HIV-2, HCV, HbsAg theo phương pháp được FDA chứng nhận. Tuy nhiên để bảo đảm an toàn tuyệt đối nên mẫu này nên được xử lý như mẫu bệnh nhân để tránh lây nhiễm.

Chỉ dùng cho phân tích trong ống nghiệm. Không được hút mẫu bằng miệng. Tuân thủ các khuyến cáo thông thường yêu cầu trong quy trình xử lý hoá chất phòng xét nghiệm.

LƯU Ý QUAN TRỌNG:

Kết quả phân tích phải được gửi đến cho RIQAS trước 17:00 GMT ngày hạn chót gửi trả kết quả. Phòng xét nghiệm nên phân tích mẫu sớm trước ngày khuyến cáo phân tích mẫu nếu cần để đảm bảo thời gian gửi trả kết quả. Kết quả phân tích trễ sẽ không được chấp nhận sau hạn chót gửi trả kết quả của mẫu tiếp theo.

TÜRKÇE

GLİKOLİZE HEMOGLOBİN (HbA1c) PROGRAMI : RQ9129

KİT ÖZELLİKLERİNİN VE ULAŞMA TARİHİNİN DOĞRULANMASI

Lütfen doğru sayıda örneğin bulunduğunu ve örneklerin görünüşlerinin aşağıda ÖZELLİKLER bölümünde belirtildiği gibi olduğunu doğrulayınız. Lütfen şişelerden hiç birinin kırık olmadığını doğrulayınız ve eğer herhangi bir uygunsuzluk varsa derhal yerel RANDOX sorumlunuzu uyarınız. Son olarak, lütfen www.riqas.net 'e giriş yaparak bu kiti hatasız teslim aldığınız tarihi doğrulayınız.

ÖZELLİKLER

Paket; 6 şişe 0.5 ml'lik liyofilize örnekten oluşmaktadır. Şişeler, örnek numaralarıyla etiketlenmiştir.

NUMUNE HAZIRLAMA / DEPOLAMA / NUMUNELERİN STABİLİTESİ

Örnekler vakumlanarak ambalajlanmıştır. Şişeyi, herhangi bir materyal kaybı olmayacak şekilde dikkatlice açınız ve kalibre edilmiş bir pipetle tam 0.5 ml'lik hacimde taze distile su ile +20°C- +25°C'de sulandırınız. Plastik kapağı yerleştiriniz, şişeyi kapatınız, şişeyi bir kaç kez alt üst ediniz ve 15 dakika oda ısısında bekletiniz. 15 dakika sonra, distile suyun tüm yüzeylerle temasını sağlamak için şişeyi hafifçe çeviriniz ve alt üst ediniz. Solüsyon homojen hale gelinceye ve liyofilize materyal tamamen çözünene kadar karıştırmaya devam ediniz. Şişeyi hafifçe alt-üst ederek liyofilize materyalin tamamen çözündüğünden emin olunuz. Çalkalamayınız. Lütfen, örneği çözdükten sonraki 2 gün içerisinde çalışınız. Çözünmüş örnekleri dondurmayınız. Örnekler kullanılmadığı zaman 2-8°C'de muhafaza edilmelidir.

NOT. Çözünmüş örneklerle, hasta örnekleriyle aynı şekilde muamele edilmelidir. Analiz metoduna bağlı olarak HbA1c analizi için örneklerle ön-işlem gerekebilir (analizör üzerinde veya manuel).

GÜVENLİK

Potansiyel olarak biyolojik tehlikeli madde. Örnekler insan kanı içerir. Bu ürünün elde edildiği insan kaynaklı materyal donor seviyesinde İnsan İmmünyetmezlik Virüsü (HIV 1, HIV 2) antikor, Hepatit B yüzey Antijeni (HbsAg), ve Hepatit C Virüs (HCV) antikoruna açısından test edilmiş ve NON-REAKTİF olarak bulunmuştur. Bu testler için FDA onaylı metotlar kullanılmıştır. Fakat yine de, hiç bir metot enfeksiyon ajanlarının yokluğu için tam garanti vermediğinden bu materyal ve tüm hasta örnekleri muhtemel enfeksiyon hastalığı taşıyıcısı varsayılarak çalışılmalı ve uygun şekilde atığa gönderilmelidir.

Sadece IN VITRO kullanım içindir. Ağızla pipetleme yapmayınız. Laboratuvar reaktiflerinin örneklenmesi için gerekli normal önlemleri uygulayınız.

*** ÖNEMLİ NOT:** Sonuçlar, RIQAS'a **SON SONUÇ GÖNDERİM TARİHİ**'nde saat 17:00'de ulaşmış olmalıdır. Eğer **ÖNERİLEN ANALİZ TARİHİ** sizin için uygun değilse, sonuç gönderim tarihine yetişmesi için için örneği daha erken analiz etmenizi öneririz. Geç sonuçlar, bir sonraki örneğin son sonuç gönderim tarihi sonrasında kabul edilmeyecektir.

SLOVENSKY

GLYCATED HAEMOGLOBIN (HbA1c) PROGRAMME: RQ9129

POTVRDENIE CHARAKTERISTIKY KITU A DÁTUMU DORUČENIA

Prosím potvrdte doručenie správneho čísla vzorky a potvrdte, či vzhľad vzoriek zodpovedá charakteristike opísanej v sekcii nižšie. Prosím potvrdte, že žiadne fľaštičky nie sú rozbité, v opačnom prípade okamžite kontaktuje svojho obchodného zástupcu. Po prihlásení na www.riqas.net potvrdte a zadajte presný dátum, kedy Vám bol kit doručený.

CHARAKTERISTIKA

Balenie obsahuje 6 fľaštičiek lyofilizovaných 0.5 ml vzoriek. Fľaštičky sú označené číslom vzorky.

PRÍPRAVA/SKLADOVANIE/STABILITA VZORIEK

Fľaštička je vákuovo uzatvorená. Otvorte fľaštičku veľmi opatrne, vyhnite sa stratám materiálu a použitím **nakalibrovannej pipety** rekonšitujte presne **0.5 ml** objemu čerstvo destilovanej vody pri teplote **+20°C to +25°C**. Zatvorte fľaštičku, niekoľko krát jemne premiešajte a nechajte odstáť pri izbovej teplote **15 minút**. Po 15 minútach vytvorené vrstvy odstráňte rotáciou a prevracaním fľaštičky. Pokračujte v miešaní kým nebude roztok homogénny a všetok lyofilizovaný materiál rekonštituovaný. Netraste fľaštičkou. Vzorky analyzujte do 2 dní po rekonštitúcii. Rekonštituované vzorky nezmrazujte. Vzorky skladujte pri teplote 2 - 8°C.

Poznámka: So vzorkami zaobchádzajte rovnakým spôsobom ako s patientskými vzorkami. V závislosti od metódy analýzy, môže byť požadovaná úprava vzoriek (analýzátorom alebo manuálne).

BEZPEČNOSŤ

Potenciálne nebezpečný materiál. Vzorky obsahujú ľudskú krv. Materiál ľudského pôvodu, ktorý bol testovaný na HIV (HIV 1 a HIV2) protilátky, HBsAg a hepatitídu C (HCV) a bol NEREAKTÍVNY. Avšak žiadna metóda nedokáže zabezpečiť absolútnu istotu pri detekcii, preto s týmto materiálom a všetkými patientskými vzorkami by sa malo zaobchádzať ako by boli schopné prenášať infekčné ochorenie.

Iba na **IN VITRO** použitie, nepipetujte ústami, vykonajte bežné bezpečnostné opatrenia vyžadované pri laboratórnych postupoch.

*** POZNÁMKA:** Výsledky musia byť odoslané do **RIQAS** do **17:00 Hod GMT** vo **FINÁLNY DÁTUM**. Ak **ODPORÚČANÝ DÁTUM ANALÝZY** neposkytuje dostatočný čas, odporúčame analýzu vzorky skôr, aby sa zabezpečilo dodržanie termínu. Výsledky prijaté po finálnom termíne nebudú akceptované.

Sep 2023



RQ9159
IMMUNOSUPPRESSANT PROGRAMME
PROGRAMME IMUNOSSUPRESSEUR
PROGRAMA IMUNOSSUPRESORES
PROGRAMA DE INMUNOSUPRESORES
PROGRAMMA IMMUNOSOPPRESSORI
PROGRAM LEKI IMMUNOSUPRESYJNE
CHƯƠNG TRÌNH NGOẠI KIỂM ỨC CHẾ MIỄN DỊCH
โปรแกรม IMMUNOSUPPRESSANT
免疫抑制剂计划
İMMÜNOSUPRESANLAR PROGRAMI

ENGLISH

IMMUNOSUPPRESSANT PROGRAMME: RQ9159

CONFIRMATION OF KIT CHARACTERISTICS AND RECEIPT DATE

Please confirm that the correct number of samples are present and that your samples have the appearance as indicated in the CHARACTERISTICS section below. Please confirm that none of the vials are broken and notify your local Randox representative immediately if there are any discrepancies. Finally, please log on to www.riqas.net to confirm the exact date on which you received this kit.

CHARACTERISTICS

The pack contains 6 vials of lyophilised material (6 x 2 ml). The vials are labelled with the sample number.

PREPARATION/STORAGE/STABILITY OF SAMPLES

The samples are sealed under vacuum. Open the vial very carefully, avoiding any loss of material and using a calibrated pipette reconstitute with an accurately measured 2 ml volume of freshly double distilled water at **+20°C to +25°C**. Replace the rubber stopper and ensure that samples are dissolved completely by swirling gently (ideally place on a roller for half an hour prior to analysis). Do not shake the vials. We recommend that the samples are run immediately following full reconstitution. The samples should be treated in the same way as patient samples.

SAFETY

Warning: Potentially Biohazardous Material

Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

For IN VITRO use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

*** IMPORTANT NOTE:** Results must arrive at **RIQAS** by **17:00 hrs GMT** on the **FINAL DATE**. If the **RECOMMENDED ANALYSIS DATE** gives insufficient time, we suggest that the sample is analysed earlier to ensure you meet the deadline. Late results will not be accepted after the final date for the next sample.

IMMUNOSUPPRESSANT PROGRAMME/ PROGRAMME IMUNOSSUPRESSEUR / PROGRAMA IMUNOSSUPRESORES /
PROGRAMA DE INMUNOSUPRESORES / PROGRAMMA IMMUNOSOPPRESSORI / PROGRAM LEKI IMMUNOSUPRESYJNE
โปรแกรม IMMUNOSUPPRESSANT / CHƯƠNG TRÌNH NGOẠI KIỂM ỨC CHẾ MIỄN DỊCH / 免疫抑制剂计划 / İMMÜNOSUPRESANLAR PROGRAMI

RETURN OF RESULTS / RETOUR DES RESULTATS / INVIO DEI RISULTATI / ENVIO DE RESULTADOS / RETORNO DOS RESULTADOS/
PRZESYLANIE WYNIKÓW / 回复结果 / GÜİ TRÁ KÉT QUÁ / SONUÇ GÖNDERİM TARİHLERİ / ODOŚLANIE WYŚLEDKÓV

CYCLE 8B / CICLO 8B / CYKL 8B / 返回结果周期 8B / CHU KỶ 8B / DÖNEM 8B / CYKLUS 8B

SAMPLE NO / ECHANTILLON NO. / N. CAMPIONE / N° DE MUESTRA / AMOSTRA Nº. / NR PRÓBK / 样品号 / ตัวอย่างตรวจที่ / MĀU SÓ / ÖRNEK NO / Č. VZORKY	RECOMMENDED ANALYSIS DATE/ DATE RECOMMANDE POUR L' ANALYSE/ DATA DI ANALISI RACCOMANDATA/ FECHA DE ANALISIS RECOMENDADA/ ZALECANA DATA WYKONANIA OZNACZENIA/ 推荐分析日期 / วันที่แนะนำให้ทำการวิเคราะห์ / NGÀY KHUYẾN CÁO PHÂN TÍCH / ÖNERİLEN ÇALIŞMA TARİHİ / ODPORÚČANÝ DÁTUM ANALÝZY	* FINAL DATE/ *DATE LIMITE/ * DATA FINALE/ *FECHA FINAL/ * DATA KOŃCOWA/ *最终日期 * วันสุดท้ายของการส่งผลกลับ / * HẠN CUỐI GỬI TRẢ KẾT QUẢ *SON SONUÇ GÖNDERİM TARİHİ / *FINALNY TERMÍN
7	11.09.23	18.09.23
8	09.10.23	16.10.23
9	13.11.23	20.11.23
10	11.12.23	18.12.23
11	15.01.24	22.01.24
12	12.02.24	19.02.24

FRANÇAIS

PROGRAMME IMUNOSSUPRESSEUR: RQ9159

CONFIRMATION DES CARACTERISTIQUES DU KIT ET DE LA DATE DE RECEPTION:

Veuillez vérifier que l'ensemble des échantillons soient présents dans le coffret et que leur apparence est conforme comme indiqué dans la section ci-dessous. De plus assurez-vous qu'aucun des flacons ne soient brisés et en informer immédiatement votre représentant Randox si cela est le cas. Enfin, il est nécessaire de se connecter à www.rigas.net pour confirmer la date exacte à laquelle vous avez reçu ce kit.

CARACTERISTIQUE

Le coffret est composé de 6 flacons de matériel lyophilisé (6 x 2 ml). Le numéro de l'échantillon est indiqué sur l'étiquette du flacon.

PREPARATION/STOCKAGE/STABILITE DES ECHANTILLONS

Les échantillons sont scellés sous vide. Ouvrir le flacon avec précaution, pour éviter la perte de matériel. Utiliser une pipette étalonnée, et mesurer 2 ml avec précision d'eau bidistillée entre +20 et +25°C. Remplacer le bouchon en caoutchouc et s'assurer que les échantillons sont dissous complètement en procédant par retournements successifs (idéalement, placer sur un rouleau pendant une demi-heure avant l'analyse). Ne pas secouer les flacons. Nous vous recommandons d'analyser les échantillons immédiatement après le temps de reconstitution. Les échantillons doivent être traités comme vos échantillons patients.

SÉCURITÉ

Produit à risque biologique

Ce matériel d'origine humaine, dont les donneurs ont été testés pour la présence d'anticorps de "l'Human Immunodeficiency Virus" (HIV 1, HIV 2), l'antigène de surface de l'Hépatite B (HbsAg), et d'anticorps du virus de l'Hépatite C (HCV) et ont été trouvés négatifs. Ces tests ont été effectués par des méthodes approuvées par la FDA (US Food and Drug Administration). Cependant, aucun test ne pouvant apporter une garantie totale sur le caractère non infectieux de ce produit.

Réservé uniquement pour un usage **IN VITRO**. Ne pas pipeter à la bouche. Respecter les précautions d'usage pour la manipulation des réactifs de laboratoire.

*** NOTE IMPORTANTE:** Les résultats **RIQAS** doivent parvenir au Département **RIQAS** au plus tard le lundi midi selon la **DATE FINALE**. Nous vous recommandons d'analyser les échantillons quelques jours avant cette date finale. Les résultats en retard ne seront pas acceptés après la date finale de l'échantillon suivant. Vous pouvez envoyer vos résultats via Riqasnet ou par e.mail à l'adresse suivante: mail@rigas.com.

PORTUGUÊS

PROGRAMA IMUNOSSUPRESORES: RQ9159

CONFIRMAÇÃO DAS CARACTERÍSTICAS DO KIT E DATA DE RECEPÇÃO

Agradecemos-lhe que confirme que recebeu o número correcto de amostras e que estas têm o aspecto descrito na secção CARACTERÍSTICAS deste documento. Verifique também, se nenhum dos frascos está partido e notifique o seu representante local da Randox caso encontre alguma discrepância. Finalmente, aceda ao www.rigas.net para confirmar a data exacta em que recebeu este kit.

CARACTERÍSTICAS

O Kit contém 6 frascos com material liofilizado (6 x 2 ml). Os frascos estão rotulados com o número da amostra.

PREPARAÇÃO/CONSERVAÇÃO/ESTABILIDADE DAS AMOSTRAS

As amostras encontram-se fechadas em vacuo. Abra o frasco cuidadosamente, evitando perdas de material e, usando uma **pipeta calibrada**, reconstitua com a **exactamente** 2 ml de água recentemente destilada a **+20°C- +25°C**. Reponha a rolha de borracha e dissolva completamente o material agitando suavemente (pode colocar os frascos no agitador durante 30 minutos antes da análise). Recomendamos que faça os testes imediatamente após a reconstituição. As amostras devem ser tratadas da mesma forma que as amostras dos doentes.

SEGURANÇA

Aviso: material com potencial risco biológico

O material de origem humana usado, foi testado ao nível do dador para os vírus HIV 1 e HIV 2, assim como para HbsAg e HCV. Os métodos usados para efectuar estes testes têm a aprovação do FDA, contudo e uma vez que nenhum método pode garantir totalmente a ausência de agentes infecciosos, este material deve ser tratado como potencialmente perigoso e eliminado respeitando as boas praticas laboratoriais.

Apenas para **IN VITRO**. Não pipete com a boca e respeite as Boas Praticas Laboratoriais para o manuseamento de material potencialmente contaminado.

*** NOTA IMPORTANTE:** Os resultados têm de chegar ao **RIQAS** até às **17:00 hr GMT** na **DATA FINAL**. Se a **DATA RECOMENDADA PARA ANÁLISE** não der tempo suficiente, sugerimos que a amostra seja analisada mais cedo para garantir o cumprimento da data limite. Resultados atrasados não serão aceites depois a data final da amostra seguinte.

ESPAÑOL

CONFIRMACION DE LAS CARACTERISTICAS DEL KIT Y LA FECHA DE RECEPCION.

Por favor, Asegúrese de que ha recibido el numero correcto de muestras y que estas cumplen con la presentación indicada en la sección "CARACTERISTICAS" que encontrara a continuación. Por favor, confirme que ninguna de las muestras ha resultado dañada y contacte a su Representante local de Randox inmediatamente en el caso de que hubiese alguna discrepancia. Por ultimo, Acceda a www.rigas.net para confirmar la fecha exacta en la que recibió el kit.

CARACTERÍSTICAS

El paquete contiene 6 frascos de muestras liofilizadas (6 x 2 ml). Los frascos están marcados con el número de la muestra.

PREPARACIÓN/ ALMACENAMIENTO/ ESTABILIDAD DE LAS MUESTRAS

Las muestras están cerradas al vacío. Abrir el frasco con mucho cuidado, para evitar cualquier pérdida de material y reconstituir con exactamente 2 ml de agua destilada obtenida recientemente y conservada entre +20°C y +25°C. Volver a colocar el tapón de goma para cerrar el frasco y asegurarse de que los componentes liofilizados estén completamente disueltos girando el frasco suavemente (idealmente debe ponerlos en una maquina girador durante media hora antes de analizar). No agitar los frascos. Recomendamos que se analice las muestras inmediatamente después de reconstitución. Debe manejar las muestras en la misma manera que las muestras de pacientes.

SEGURIDAD**Advertencia: Material Potencialmente Biopeligroso**

El material de base humana de donde vienen estas muestras ha sido analizado, siendo negativo para anticuerpos HIV 1, HIV 2, HbsAg y HCV. Hemos usado métodos aprobados por la FDA para realizar estas pruebas. Sin embargo, ya que ningún método pueda ofrecer una seguridad completa en cuanto a la ausencia de agentes infecciosos, se debe manejar este material y las muestras de pacientes como si fueran capaces de transmitir enfermedades infecciosas y debe tirarlos de manera apropiada.

Sólo para IN VITRO. No pipetear con la boca. Debe seguir las precauciones normales para el manejo de reactivos de laboratorio.

*** NOTA IMPORTANTE:** Los resultados deben arribar a **RIQAS** a las **17:00 horas GMT** en la **FECHA FINAL**. Si la **FECHA RECOMENDADA PARA ANALISIS** dada es insuficiente, le sugerimos que analice la muestra antes para asegurarse que la tenga lista en la fecha final. Los resultados tardíos nos serán aceptados después de la fecha final de la siguiente muestra.

ITALIANO**PROGRAMMA IMMUNOSUPPRESSORI: RQ9159****CONFERMA DELLE CARATTERISTICHE DEL KIT E DELLA DATA DI RICEZIONE**

Si prega di confermare che sia presente il numero corretto di campioni e che i vostri campioni siano come indicato nella sezione CARATTERISTICHE qui sotto. Confermare che nessuna fiala sia rotta ed informare immediatamente il rappresentante Randox locale se ci fossero delle discrepanze. Infine, si prega di accedere al sito www.rigas.net per confermare la data esatta in cui si è ricevuto questo kit.

CARATTERISTICHE

Il pacco contiene 6 fiale di materiale liofilo (6 x 2 ml). Le fiale sono etichettate con il numero del campione.

PREPARAZIONE/CONSERVAZIONE/ STABILITA' DEI CAMPIONI

I campioni sono chiusi sottovuoto. Aprire la fiala con estrema cautela, evitando qualsiasi perdita di materiale e usando una pipetta calibrata ricostituire con un volume accuratamente misurato di 2 ml di acqua appena bidistillata a **+20°C to +25°C**. Rimettere il tappo di gomma e assicurarsi che i campioni siano dissolti completamente agitando delicatamente (l'ideale sarebbe utilizzare un agitatore per mezz'ora prima dell'analisi). Raccomandiamo di dosare i campioni immediatamente dopo la ricostituzione. I campioni devono essere trattati nello stesso modo in cui vengono trattati i campioni di pazienti.

SICUREZZA**Attenzione: materiale potenzialmente pericoloso**

Il materiale di origine umana da cui è derivato questo prodotto è stato testato sui donatori, e ha dato **ESITO NEGATIVO**, per l'anticorpo del virus da Immunodeficienza Umana (HIV 1, HIV 2), per l'Antigene di Superficie del virus dell'Epatite B (HbsAg), e per l'anticorpo del virus dell'Epatite C (HCV). Per questi test sono stati usati metodi approvati dall'FDA. Poiché nessun metodo di indagine può dare assoluta garanzia di assenza di questi agenti infettivi, si raccomanda di trattare e smaltire il prodotto e tutti i campioni dei pazienti con cautela.

Solo per uso **IN VITRO**. Non utilizzare pipette a bocca. Utilizzare le normali precauzioni necessarie per la manipolazione di reagenti di laboratorio.

*** NOTA IMPORTANTE:** I risultati devono arrivare a **RIQAS** entro le 17:00 GMT dell' **ULTIMA DATA**. Se la **DATA RACCOMANDATA PER L'ANALISI** non fornisce tempo a sufficienza, suggeriamo di analizzare il campione prima per essere certi di rispettare la scadenza. Risultati in ritardo non saranno accettati dopo l'ultima data del campione successivo.

POLSKI

POTWIERDZENIE CHARAKTERYSTYKI ZESTAWU I DATY ODBIORU

Prosimy o potwierdzenie, że zestaw zawiera odpowiednią ilość próbek i Państwa próbki wyglądają tak, jak w podanej poniżej CHARAKTERYSTYCE. Prosimy o potwierdzenie, że żadna z próbek nie jest zbita, a jeśli są jakiegokolwiek niezgodności prosimy o niezwłoczne zgłoszenie tego lokalnemu przedstawicielowi.

Następnie prosimy o zalogowanie się na www.riqas.net w celu potwierdzenia dokładnej daty otrzymania zestawu.

CHARAKTERYSTYKA

Opakowanie zawiera 6 fiolek próbek liofilizowanych (6 x 2 ml). Fiolki są oznakowane numerem próbki.

PRZYGOTOWANIE/PRZECHOWYWANIE/STABILNOŚĆ PRÓBEK

Próbki są zamknięte metodą próżniową. Otworzyć fiolkę bardzo ostrożnie, unikając utraty materiału i rekonstruować w dokładnie odmierzonej objętości 2 ml świeżo podwójnie destylowanej wodzie w temperaturze od +20 do +25°C. Umieścić gumowy korek i upewnić się, czy próbka uległa rozpuszczeniu poprzez delikatne rolowanie (najlepiej umieścić próbkę na mieszadle na pół godziny przed oznaczeniem). Proszę nie wstrząsać fiolką. Wskazane jest wykonanie oznaczenia natychmiast po wykonaniu powyższej rekonstrukcji.

Zaleca się aby postępować z próbką tak samo jak z materiałami pobranymi od pacjentów.

BEZPIECZEŃSTWO

Ostrożnie: Materiał potencjalnie szkodliwy biologicznie.

Próbki zawierają krew ludzką. Każdy dawca został przebadany na obecność przeciwciał wirusów HIV1 i HIV2 oraz antygenu powierzchniowego zapalenia wątroby typu B (Hbs Ag) i typu C (HCV). Próbki dały wynik negatywny. Przeprowadzone badania są potwierdzone przez FDA. Jednakże, żadna metoda nie daje całkowitej pewności nieobecności czynników zakaźnych, dlatego ten materiał i wszystkie próbki pobrane od pacjentów powinny być traktowane jako potencjalne źródło chorób zakaźnych.

Tylko do *in vitro*. Nie należy pipetować ustami. Zachować ostrożność wymaganą przy używaniu odczynników laboratoryjnych.

***UWAGA:** Wyniki muszą dotrzeć do RIQAS do godziny 17:00 czasu GMT w dniu DATY FINALNEJ. Termin ten dotyczy użytkowników programu RIQASnet. Jeżeli ZALECANA DATA OZNACZENIA jest zbyt późna, sugeruje się przeprowadzenie wcześniejszej analizy, aby uzyskać czas na przesłanie wyników. Spóźnione wyniki przesłane po dacie finalnej następnej próbki nie zostaną przyjęte.

ภาษาไทย

โปรแกรม IMMUNOSUPPRESSANT: RQ9159

ยืนยันคุณลักษณะชุด kit และวันที่ได้รับชุด kit

โปรดยืนยันว่าจำนวนของตัวอย่างถูกต้อง เป็นตัวอย่างในปัจจุบันและตัวอย่างของท่านมีลักษณะตามที่ระบุไว้ในคุณลักษณะด้านล่าง

โปรดยืนยันว่าไม่มีขวดแตกและให้แจ้งตัวแทนจำหน่ายของท่านทันทีหากมีความผิดปกติใดๆ โปรดเข้าสู่ระบบ www.riqas.net เพื่อยืนยันวันที่ท่านได้รับชุดkit

คุณลักษณะ

ใน 1 กล่อง ประกอบด้วยตัวอย่างที่เป็นผงแห้งบรรจุในขวดขนาด 2 มิลลิลิตร จำนวน 6 ขวด (6 x 2 ml.) โดยแต่ละขวดจะมีหมายเลขตัวอย่างระบุไว้ที่ข้างขวด

การเตรียมตัวอย่างตรวจ / การเก็บรักษา / ความเสถียรของตัวอย่าง

ตัวอย่างปิดผนึกภายใต้สุญญากาศ เปิดแต่ละขวดอย่างระมัดระวัง หลีกเลี่ยงการสูญเสียของตัวอย่าง และใช้ไปดเปิดที่เคลือบแล้ว ละลายตัวอย่างด้วย freshly double distilled water 2 มิลลิลิตร ที่อุณหภูมิ 20-25 °C ปิดจุกยางปิดจุกยางและให้แน่ใจว่าตัวอย่างมีการละลายอย่างสมบูรณ์โดยการหมุนขวดเป็นวงกลมอย่างช้าๆ (swirling) (วางอยู่บน roller ครั้งชั่วโมงก่อนทำการวิเคราะห์) ห้ามเขย่าขวด เมื่อละลายอย่างสมบูรณ์แล้วให้ทำการวิเคราะห์ตัวอย่างทันที ควรทำการตรวจวิเคราะห์เช่นเดียวกับการตรวจตัวอย่างผู้ป่วย

ความปลอดภัย

ข้อควรระวัง: Potentially Biohazardous Material

ตัวอย่างตรวจได้มาจาก human source ของผู้บริจาคโลหิต ซึ่งได้ทำการตรวจว่ามีความปลอดภัยจากแอนติบอดีของไวรัส HIV (HIV1, HIV2) HBs Ag และ HCV Antibody โดยมีผลการตรวจเป็น Non-Reactive และได้ใช้วิธีการที่ได้รับการพิสูจน์จาก FDA ในการตรวจวัด test ต่างๆ อย่างไรก็ตามไม่มีวิธีการใด ที่จะสามารถให้ความมั่นใจได้ว่าความปลอดภัยจาก infectious agents

ดังนั้นควรทำการตรวจวิเคราะห์ตัวอย่าง และ ตัวอย่างจาก ผู้ป่วยด้วยความระมัดระวัง

สำหรับ IN VITRO เท่านั้น อย่าเปิดทางปาก ข้อควรระวังให้ปฏิบัติตาม normal precautions สำหรับน้ำยาวิเคราะห์

หมายเหตุ สำคัญ ผลจะต้องถึง RIQAS ในเวลา 17.00 hrs. GMT ของวันสุดท้ายของการส่งผลกลับ (Final Date) ขอแนะนำให้ทำการวิเคราะห์ตัวอย่าง ก่อนจะถึงวันสุดท้ายของการส่งผลกลับ (Final Date) LATE RESULTS หรือการส่งผลช้า จะไม่ได้รับการประเมิน ถ้าส่งผลหลังจาก Final Date ของ sample ถัดไป

TIẾNG VIỆT

CHƯƠNG TRÌNH NGOẠI KIỂM ÚC CHẾ MIỄN DỊCH: RQ9159

XÁC NHẬN VỀ ĐẶC ĐIỂM CỦA BỘ KIT VÀ NGÀY NHẬN MẪU

Xin hãy xác nhận đúng số lượng mẫu và bề mặt ngoài của mẫu giống như đặc điểm nêu phía dưới. Hãy xác nhận không có mẫu nào bị vỡ và thông báo cho đại diện phân phối ngay lập tức nếu xuất hiện dấu hiệu khác thường của mẫu. Cuối cùng, hãy đăng nhập vào www.riqas.net để xác nhận ngày bạn nhận được mẫu.

ĐẶC ĐIỂM

Mỗi hộp bao gồm 6 lọ dạng đông khô, mỗi lọ 2ml và được dán nhãn số theo thứ phân tích.

CHUẨN BỊ/BẢO QUẢN/ĐỘ BỀN CỦA MẪU

Lọ mẫu được đóng nắp chân không. Mở nắp lọ cẩn thận tránh làm thất thoát, pha loãng với chính xác 2ml nước cất hai lần ở +20°C – +25°C. Đẩy nút cao su và đảm bảo rằng mẫu được hòa tan hoàn toàn bằng cách xoay nhẹ nhàng (tốt nhất là để trên máy lắc trộn trong 30 phút trước khi phân tích). Chú ý không được lắc mạnh. Chúng tôi khuyến cáo mẫu nên được phân tích ngay sau khi thực hiện đầy đủ các bước hoàn nguyên. Mẫu được xử lý và phân tích giống mẫu bệnh nhân.

ĐỘ AN TOÀN

Cảnh báo: Khả năng có độc tính sinh học với nguồn vật liệu

Mẫu có nguồn gốc từ người và đều được kiểm tra không có phản ứng với kháng thể HIV (HIV 1 & HIV 2), HbsAg, HCV. Phương pháp kiểm tra được chấp nhận bởi tổ chức FDA. Tuy nhiên không có phương pháp kiểm tra nào có thể đảm bảo tuyệt đối sự âm tính của tác nhân truyền nhiễm. Để bảo đảm an toàn tuyệt đối, mẫu này và toàn bộ mẫu bệnh nhân phải được thao tác xử lý giống như mẫu truyền nhiễm.

Chỉ dùng cho phân tích trong ống nghiệm. Không được hút mẫu bằng miệng. Tuân thủ các khuyến cáo thông thường yêu cầu trong quy trình xử lý hoá chất phòng xét nghiệm.

LƯU Ý QUAN TRỌNG:

Kết quả phân tích phải được gửi đến cho RIQAS trước 17:00 GMT ngày hạn chót gửi trả kết quả. Phòng xét nghiệm nên phân tích mẫu sớm trước ngày khuyến cáo phân tích mẫu nếu cần để đảm bảo thời gian gửi trả kết quả. Kết quả phân tích trễ sẽ không được chấp nhận sau hạn chót gửi trả kết quả của mẫu tiếp theo.

中文

免疫抑制剂计划: RQ9159

确认试剂盒特性和接收日期

请确认样品的数量正确及外观如下面特性描述一致。请确认没有小瓶破损，如果有任何差异请立即通知当地的朗道的代表。最后，请登录 www.riqas.net 确认您用来接收该试剂盒的确切日期

特性

此试剂盒包含 6 瓶冻干材料（6×2 毫升）。每瓶上标注了样本编号。

样本的配制/储存/稳定性

样本是在真空密封状态。小心打开每个小瓶，避免损失任何材料，在+20°C~+25°C环境下使用经校准的移液器准确测量的 2ml 新鲜蒸馏水来复溶每瓶样本。除去橡胶塞，并确保样本通过涡旋轻轻完全溶解（理想状态下在分析前放在滚筒上半小时）。不要摇晃瓶子。我们建议完全复溶后立即检测样本。样本处理应与患者标本相同。样本不使用时，

安全

警告：具有潜在生物安全风险的材料

这款产品中所使用的有献血者获得的人源物质已经进行了人类免疫缺陷病毒（HIV1, HIV2）抗体、乙型肝炎抗原（HBsAg）和丙型肝炎病毒（HCV）抗体检测，结果为阴性。这些试验使用的是 FDA 批准的方法。然而，由于感染性病原体的缺失，没有方法能够完全保证安全，所以这种物质和所有患者标本应如同传染病传播的处理和做出相应的处置。

用于体外诊断。不要用嘴吸允。练习进行处理，需要实验室试剂的常规注意事项。

***重要提示：**结果必须在最后期限 17:00GMT 反馈给 RIQAS。如果推荐分析日期给出的时间不足，我们建议提早进行样品分析，以确保您复合最后期限。晚于截止日期的结果将不被接受。

TÜRKÇE

IMMÜNOSUPRESANLAR PROGRAMI: RQ9159

KİT ÖZELLİKLERİNİN VE ULAŞMA TARİHİNİN DOĞRULANMASI

Lütfen doğru sayıda örneğin bulunduğunu ve örneklerin görünüşlerinin aşağıda ÖZELLİKLER bölümünde belirtildiği gibi olduğunu doğrulayınız. Lütfen şişelerden hiç birinin kırık olmadığını doğrulayınız ve eğer herhangi bir uygunsuzluk varsa derhal yerel RANDOX sorumlunuzu uyarınız. Son olarak, lütfen www.riqas.net 'e giriş yaparak bu kiti hatasız teslim aldığınız tarihi doğrulayınız.

ÖZELLİKLER

Paket, 6 şişe lyofilize materyali içerir (6 x 2 ml). Şişeler; örnek numaraları ile etiketlenmiştir.

NUMUNE HAZIRLAMA / DEPOLAMA / NUMUNELERİN STABİLİTESİ

Örnekler vakumlanarak ambalajlanmıştır. Şişeyi, herhangi bir materyal kaybı olmayacak şekilde dikkatlice açınız ve kalibre edilmiş bir pipetle tam 2 ml'lik hacimde taze distile su ile **+20°C -+25°C**'de sulandırınız. Plastik tıpayı yerleştiriniz ve hafifçe çevirerek örneklerin tam olarak çözünmesini sağlayınız. (İdeali analizden yarım saat önce bir karıştırıcı üzerine koymaktır). Çalkalamayınız. Örnekler tam olarak çözününce hemen çalışmanız önerilmektedir. Örneklerle, hasta örnekleri ile aynı şekilde muamele edilmelidir.

GÜVENLİK

Uyarı: Potansiyel olarak biyolojik tehlikeli madde

Bu ürünün elde edildiği insan kaynaklı materyal donor seviyesinde İnsan İmmünyetmezlik Virüsü (HIV 1, HIV 2) antikor, Hepatit B yüzey Antijeni (HbsAg), ve Hepatit C Virüsü (HCV) antikor açısından test edilmiş ve NON-REAKTİF olarak bulunmuştur. Bu testler için FDA onaylı metotlar kullanılmıştır. Fakat yine de, hiç bir metot enfeksiyon ajanlarının yokluğu için tam garanti veremediğinden bu materyal ve tüm hasta örnekleri muhtemel enfeksiyon hastalığı taşıyıcısı varsayılarak çalışılmalı ve uygun şekilde atığa gönderilmelidir.

Sadece IN VITRO kullanım içindir. Ağızla pipetleme yapmayınız. Laboratuvar reaktiflerinin örnekleme için gerekli normal önlemleri uygulayınız.

*** ÖNEMLİ NOT:** Sonuçlar, RIQAS'a **SON SONUÇ GÖNDERİM TARİHİ**'nde saat **17:00**'de ulaşmış olmalıdır. Eğer **ÖNERİLEN ANALİZ TARİHİ** sizin için uygun değilse, sonuç gönderim tarihine yetiştirmesi için için örneği daha erken analiz etmenizi öneririz. Geç sonuçlar, bir sonraki örneğin son sonuç gönderim tarihi sonrasında kabul edilmeyecektir.

SLOVENSKY

IMMUNOSUPPRESSANT PROGRAMME: RQ9159

POTVRDENIE CHARAKTERISTIKY KITU A DÁTUMU DORUČENIA

Prosim potvrdte doručenie správneho čísla vzorky a potvrdte, či vzhľad vzoriek zodpovedá charakteristike opísanej v sekcii nižšie. Prosim potvrdte, že žiadne fľaštičky nie sú rozbité, v opačnom prípade okamžite kontaktuje svojho obchodného zástupcu. Po prihlásení na www.riqas.net potvrdte a zadajte presný dátum, kedy Vám bol kit doručený.

CHARAKTERISTIKA

Balenie obsahuje 6 fľaštičiek lyofilizovaných vzoriek (6 x 2 ml). Fľaštičky sú označené číslom vzorky.

PRÍPRAVA/SKLADOVANIE/STABILITA VZORIEK

Fľaštička je vákuovo uzatvorená. Otvorte fľaštičku veľmi opatrne, vyhnite sa stratám materiálu a použitím **nakalibrovanej pipety** rekonštituujte presne **2 ml** objemu čerstvo destilovanej vody pri teplote **+20°C to +25°C**. Zatvorte gumenou zátkou a jemným vírením sa uistite, že vzorky sú úplne rozpustené (ideálne umiestnite na miešadlo, roler, na pol hodinu pred samotnou analýzou). Nevracajte fľaštičkami. Odporúčame analýzu vzoriek okamžite po úplnej rekonštitúcii. So vzorkami zaobchádzajte rovnakým spôsobom ako s patientskými vzorkami.

BEZPEČNOSŤ

Upozornenie: Potenciálne biohazardný materiál

Tento materiál je vyrobený z ľudského zdroja a bol testovaný na úrovni darcu na Human Immunodeficiency Virus (HIV 1, HIV 2) protilátky, Hepatitídu B povrchový antigen (HbsAg), a protilátky Hepatitídy C (HCV) a bol preukázaný ako NEREAKTÍVNY. Boli použité metódy schválené federáciou FDA. Keďže žiadna metóda nezabezpečí úplnú dôveryhodnosť, zaobchádzajte s materiálom a všetkým vzorkami pacientov ako so vzorkami, ktoré sú schopné prenášať infekčné ochorenia.

Iba na **IN VITRO** použitie. Neipetujte ústami. Vykonajte bežné opatrenia vyžadované pri manipulácii s laboratórnymi reagensiami.

*** POZNÁMKA:** **Výsledky musia byť odoslané do RIQAS do 17:00 Hod GMT vo FINÁLNY DÁTUM. Ak ODPORÚČANÝ DÁTUM ANALÝZY neposkytuje dostatočný čas, odporúčame analýzu vzorky skôr, aby sa zabezpečilo dodržanie termínu. Výsledky prijaté po finálnom termíne nebudú akceptované.**

July 2023

RANDOX

RANDOX INTERNATIONAL QUALITY ASSESSMENT SCHEME



RIQAS



RIQAS

THE LARGEST INTERNATIONAL EQA SCHEME
WITH OVER 75,000 LAB PARTICIPANTS



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Whilst every attempt is made to ensure that information is accurate and up-to-date, some information is subject to change.
Please contact marketing@randox.com for current details.

BENEFITS

Delivering a comprehensive yet cost effective EQA solution, RIQAS will help meet regulatory requirements and increase confidence in test system accuracy.



Large Database of Users

- A high level of participation means peer group numbers are maximised whilst ensuring availability of data for a wide range of instruments and methods.



User-friendly Reports

- Simple, one page per parameter format, enables at-a-glance performance assessment, saving valuable laboratory time.
- Complimentary multi-instrument and interlaboratory reports allow comparative performance assessment of all laboratory systems and multiple connected laboratories.
- End-of-Cycle reports, summarising performance compared to the previous cycle, allows you to identify improvements in quality over time.



Cost Effective

- Our extensive range of multi-analyte programmes will reduce the number of individual programmes required to cover your test menu, saving both time and money.
- Reduced parameter options for selected programmes offer greater flexibility, ensuring suitability for laboratories of all sizes and budgets.
- Register up to five instruments per programme (volume permitting) at no extra cost for comparative performance assessment.



Frequency

- Frequent reporting allows early identification of system errors and implementation of any necessary corrective actions with minimum disruption to the lab.
- With a turnaround of less than 72 hours for most reports, corrective action can be implemented earlier, potentially reducing costly errors with patient results.



High Quality Samples

- Samples spanning clinically relevant levels allow identification of concentration related biases, helping to ensure accurate instrument performance.
- Human samples free from interfering preservatives increase confidence that EQA performance mirrors the performance of patient samples.
- Reference method values are provided in the Clinical Chemistry programme for selected parameters and lots, while for the Immunosuppressant programme they are provided for all parameters and lots.



Highly Accredited

- Programmes accepted by National and International accreditation bodies worldwide.
- Participant certificates provide evidence of participation in a reputable EQA scheme.

RIQAS is the largest international EQA scheme in the world. It is used by more than 75,000 laboratory participants in 136 countries. 36 programmes are currently available.

RIQAS Programmes

- Ammonia/Ethanol
- Anti-Müllerian Hormone (AMH)
- Anti-TSH Receptor
- Blood Gas
- BNP
- Cardiac
- Cardiac Plus
- Cerebrospinal Fluid (CSF)
- Clinical Chemistry
- Coagulation
- CO-Oximetry
- CYFRA 21-1
- Cytokines
- ESR
- Glycated Haemoglobin (HbA1c)
- Haematology
- Human Urine
- Immunoassay
- Immunoassay Speciality 1
- Immunoassay Speciality 2
- Immunosuppressant Drugs
- Lipids
- Maternal Screening
- Microbiology (Bacterial Identification)
- Neonatal Bilirubin
- Serology (Anti-SARS-CoV-2)
- Serology Epstein Barr Virus (EBV)
- Serology (HIV/Hepatitis)
- Serology (Syphilis)
- Serology (ToRCH)
- Serum Indices
- Specific Proteins
- Sweat Testing
- Therapeutic Drugs
- Urinalysis
- Urine Toxicology

Accreditation

- RIQAS provides certificates as proof of EQA participation and performance for laboratory accreditation purposes.
- RIQAS is a UKAS accredited Proficiency Testing Provider, No. 0010, and is accredited to ISO/IEC 17043:2010, 'Conformity Assessment- General Requirements for Proficiency Testing'.
- Accreditation to ISO/IEC 17043:2010 highlights the superior quality and excellence of RIQAS.

UK Performance Surveillance

- Recognised by the Quality Assurance in Pathology Committee (QAPC).
- Recognised by various National Quality Assurance Advisory Panels (NQAAP).

Independent Advisory Panel

RIQAS participants have access to an independent advisory panel consisting of scientific and clinical experts. This ensures professional and ethical conduct of the scheme and participant confidentiality.

**RIQAS support staff are on hand to offer
 advice and troubleshoot technical queries.**

RIQAS REPORTS

RIQAS reports are presented in a user-friendly, one page per parameter format. This allows easy interpretation of your analytical performance.

RIQAS Reports

- Statistical breakdown by all methods, your method and, where applicable, your instrument, including running means for the last 10 samples.
- Compare your instrument group, method group and all methods using the histogram.
- Identify trends, biases and precision problems using the visual charts.
- The Target Score chart uniquely grades your performance in a moving window over the last 20 samples, including the previous cycle.
- At-a-glance summary page for all parameters in the programme.
- Compare your result with statistically robust consensus means.
- Identify acceptable and poor performance using fit-for-purpose performance indicators:
 - SDI
 - %Deviation
 - Target Score



Summary CSV Files

It is possible to receive an additional summary of your report statistics, acceptable limits and performance indicators as a .csv file for every sample (*available for quantitative reports only*).

Multi-Instrument Reports

Laboratories can register up to five instruments at no extra cost. Individual reports for each instrument plus a unique multi-instrument report are provided. The multi-instrument report plots the performance of each individual instrument on a single, colour coded Levey-Jennings chart, ensuring instant identification of any differences in instrument performance. Additional sample packs may be ordered as required if volume supplied is insufficient for the registered instruments.

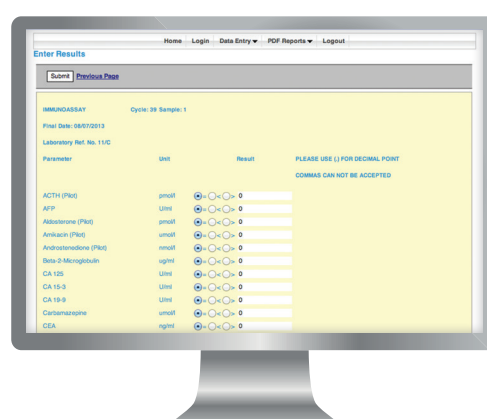
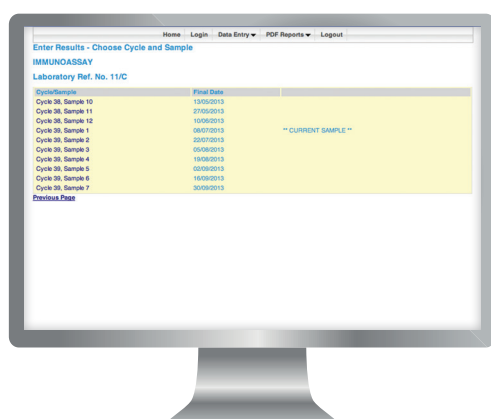
Laboratory Group Reports

The group reporting facility enables laboratory groups or chains to monitor the performance of satellite sites. Each affiliated laboratory will receive their individual reports with the group supervisor also receiving a summary report comparing each laboratory in the network.

WEB-BASED DATA TRANSFER

RIQAS.Net offers easy, direct access for the submission of results and retrieval of reports direct from the RIQAS host server.

- Available in multiple languages.
- Confidentiality and security is maintained through the use of password protected access.
- Submit current, corrected and future results (normal policies apply), directly into the RIQAS database. Receipt of results is confirmed by e-mail.
- Multi-lingual registration identifier provides simple identification of multiple registrations.
- Additions and changes to assay details can be made quickly and easily online.
- Requests for new method, instrument and reagent codes can be made online.
- Reports are emailed in PDF format as soon as they are prepared.
- Reports for the previous two cycles can be downloaded from the website.
- View, print, store or distribute reports as you wish.
- Update your laboratory's certificate of participation details in multiple languages.
- All that is required is web access, Adobe Reader (for viewing reports) and a valid password to access the system.
- No additional software required.



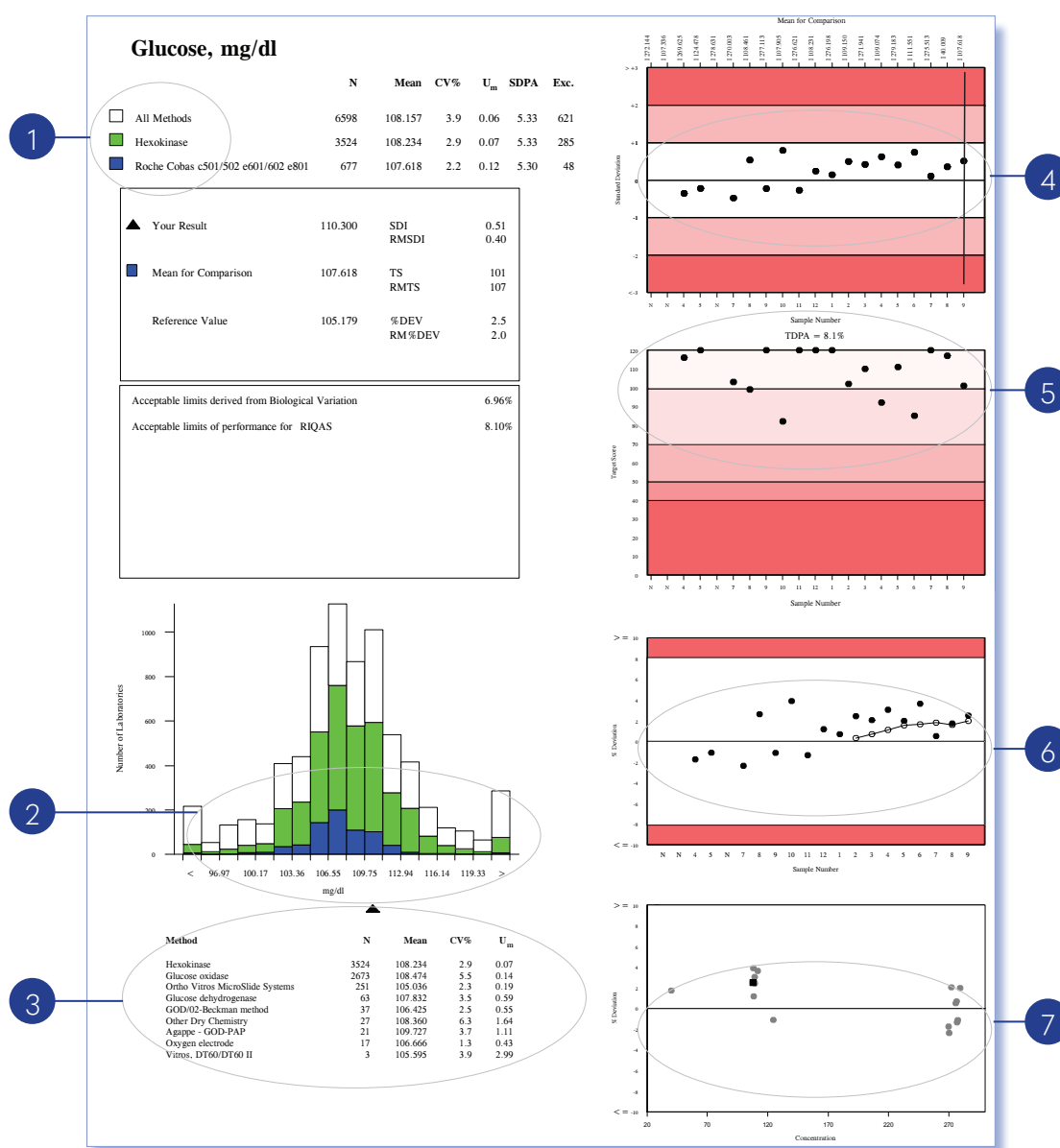
PARTICIPATION IN RIQAS

Participation in RIQAS follows these simple steps:



STANDARD REPORT

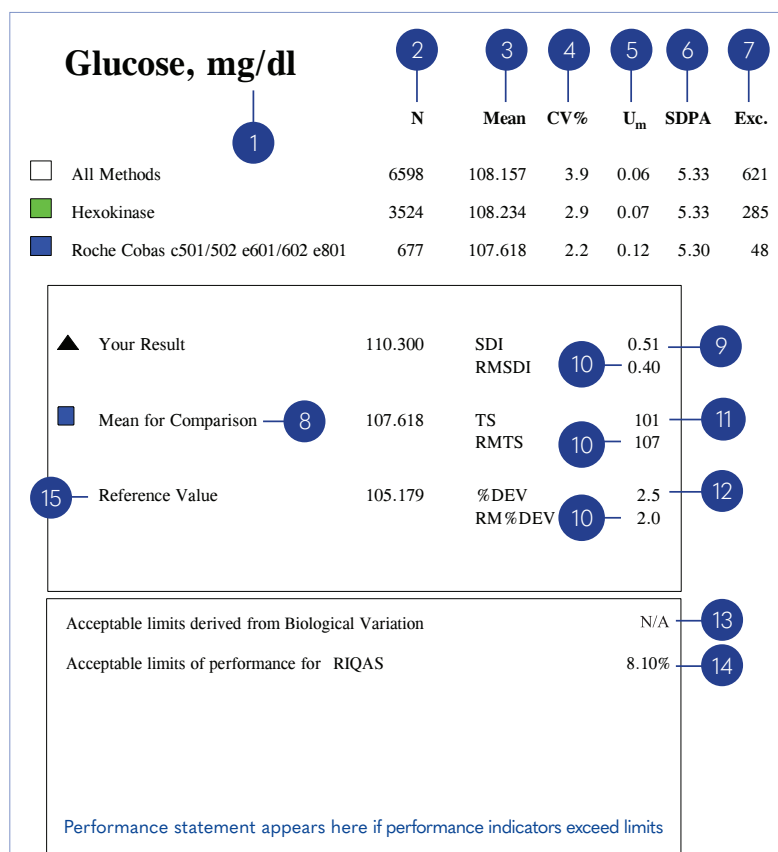
Performance data is presented in a one page format with up to seven sub-reports.



- Text Section Chart:** Statistics for all methods, your method and instrument group (programme specific).
- Histogram Chart:** Method and instrument comparison.
- Multi-Method Stat Section Chart:** Enables assessment of the performance of each method.
- Levey-Jennings Chart:** Details features of your laboratory's performance.
- Target Score Chart:** This unique chart provides a numerical index of performance, allowing at-a-glance assessment.
- %Deviation by Sample Chart:** Helps to identify trends and shifts in performance.
- %Deviation by Concentration Chart:** Rapid assessment of concentration related biases.

TEXT SECTION

The text section summarises the statistical information for each parameter.



RIQAS performance indicators include SDI, Target Score and %Deviation.

Acceptable performance criteria:

SDI < 2
Target score ≥ 50
%Deviation ≤ defined acceptable limits

- 1 Report is presented in your chosen unit.
- 2 Number of returned results used to generate Mean for Comparison.
- 3 Average value of all laboratories' results.
- 4 Coefficient of Variation.
- 5 Uncertainty associated with the Mean for Comparison.

$$U_m = \frac{1.25 \times SD}{\sqrt{n}}$$
- 6 SDPA = Standard Deviation for Performance Assessment, calculated from the Target Deviation for Performance Assessment (TDPA) and the Mean for Comparison.

$$SDPA = \frac{TDPA \times \text{Mean for Comparison}}{t\text{-value} \times 100}$$

t-value = factor which represents the % of poor performers reflected in the TDPA (t-value ~ 1.645 when ~10% laboratories achieve poor performance), SDPA is combined with U_m, where appropriate.

If U_m > (0.3 x SDPA) then $SDPA_{\text{adjusted}} = \sqrt{(U_m^2 + SDPA^2)}$ and the reported value is suffixed with "a"

If U_m is less than (0.3 x SDPA) then $SDPA_{\text{adjusted}} = SDPA$
- 7 After statistical reduction, some results are excluded from the mean for comparison.
- 8 Ideally this will be your instrument group mean. If N<5 for instrument group, your method group mean is selected as Mean for Comparison.
- 9 Standard Deviation Index = $\frac{\text{Your Result} - \text{Mean for Comparison}}{SDPA_{\text{adjusted}}}$
- 10 Running Mean average of the last 10 performance indicators is used to monitor performance over time and concentration range.
- 11 Target Score - The closer a value is to 120, the better the performance.

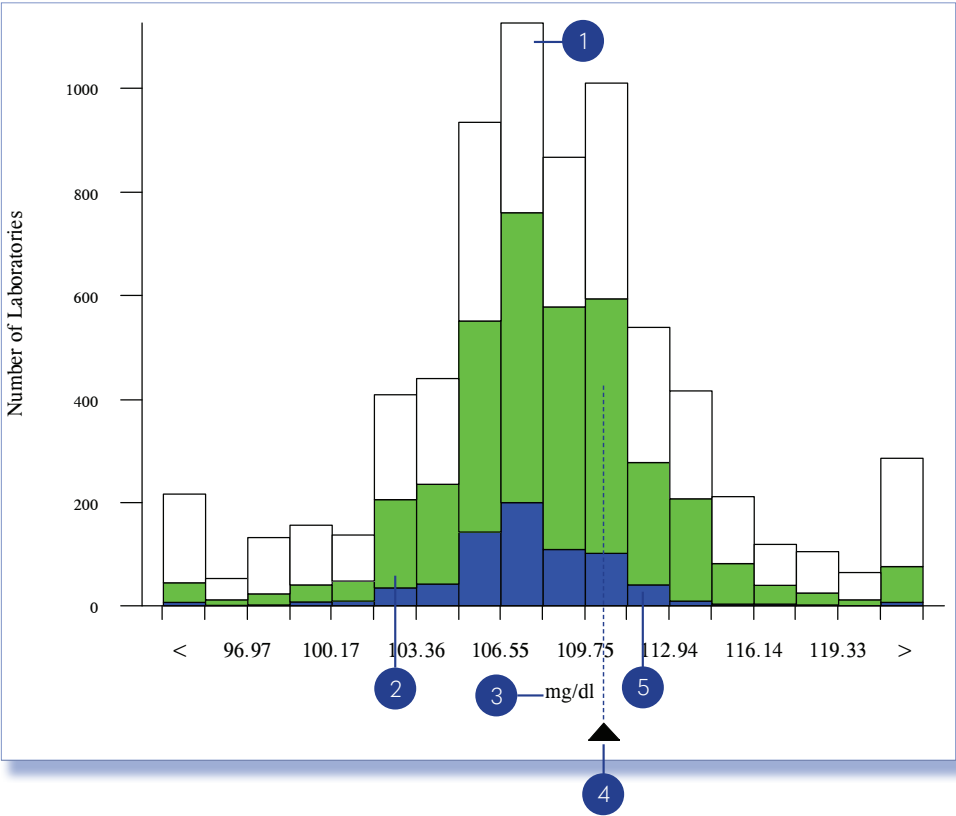
$$TS = \log_{10} \left(\frac{3.16 \times TDPA}{|\%Dev|} \right) \times 100$$
- 12 %Deviation from the Mean for Comparison -

$$\%Dev = \frac{\text{Your Result} - \text{Mean for Comparison}}{\text{Mean for Comparison}} \times 100$$

The closer the value is to zero, the better the performance.
- 13 Biological Variation - Not currently available - please review online.
- 14 Performance limit set for this parameter.
- 15 Reference values quoted for information purposes, where applicable.

HISTOGRAM

The Bar Graph is intended as a quick visualisation of how your lab’s result compares to the method mean, instrument mean and all method mean.



- 1

Total of 1126 laboratories reported values between 106.55 & 108.15.
- 2

200 laboratories reported values between 101.77 & 103.36 in your method group.
- 3

RIQAS reports show your unit of measurement.
- 4

Your result is indicated by the black triangle.
- 5

41 laboratories reported values between 111.35 & 112.94 in your instrument group.

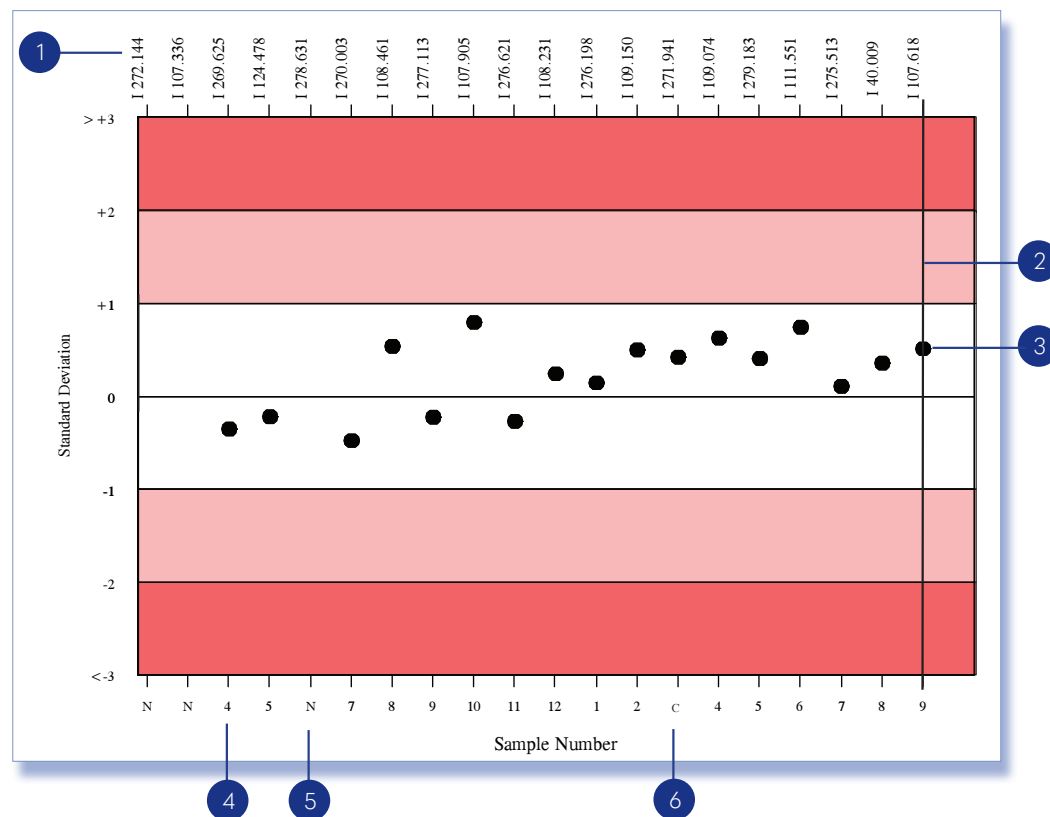
MULTI-METHOD STAT SECTION

This section provides an easy way of assessing the performance of other methods used to analyse the parameter in question.

Method	N	Mean	CV%	U _m
Hexokinase	3524	108.234	2.9	0.07
Glucose oxidase	2673	108.474	5.5	0.14
Ortho Vitros MicroSlide Systems	251	105.036	2.3	0.19
Glucose dehydrogenase	63	107.832	3.5	0.59
GOD/02-Beckman method	37	106.425	2.5	0.55
Other Dry Chemistry	27	108.360	6.3	1.64
Agappe - GOD-PAP	21	109.727	3.7	1.11
Oxygen electrode	17	106.666	1.3	0.43
Vitros, DT60/DT60 II	3	105.595	3.9	2.99

LEVEY-JENNINGS CHART

SDIs reflect laboratory performance in relation to fit-for-purpose SDPAs and are useful to monitor performance over time. Acceptable performance is $SDI < 2$.



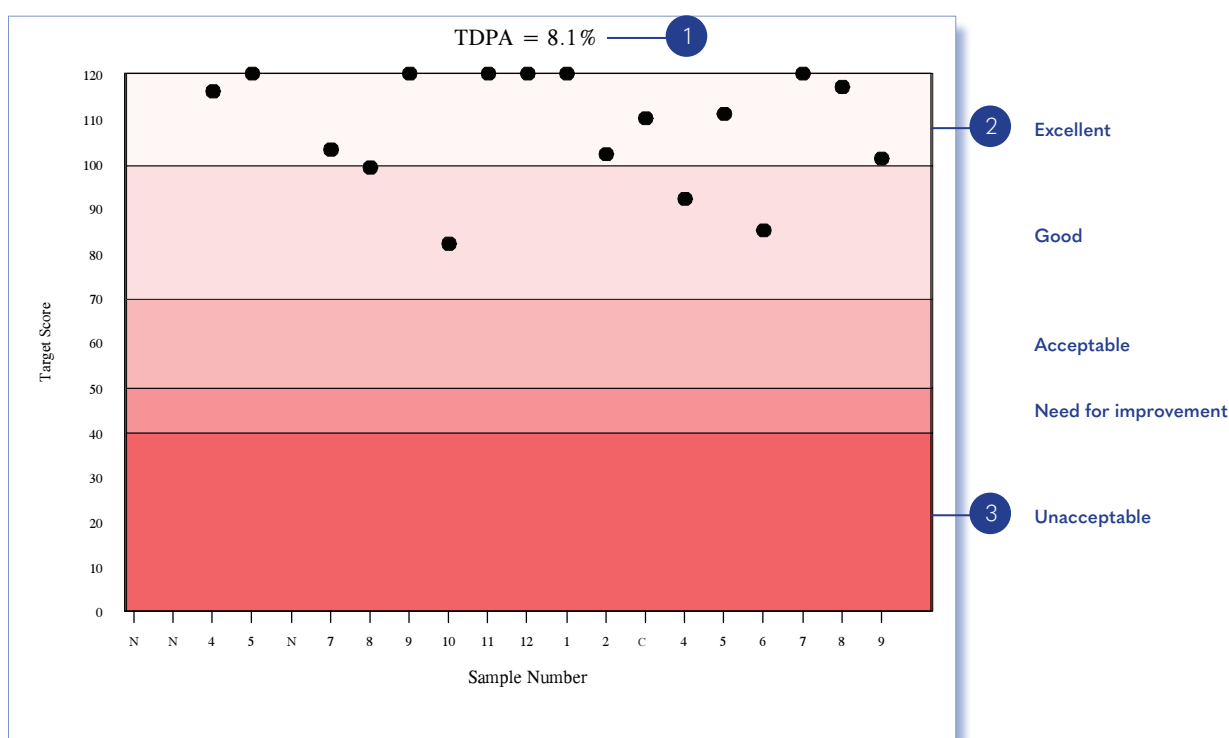
- 1 The Mean for Comparison for each sample is indicated at the top of the chart. This allows easy assessment of concentration related bias:
 I: Instrument mean
 M: Method mean
 A: All method mean
- 2 This line indicates a change in registration details for this parameter.
- 3 Your SDI (Standard Deviation Index).

- 4 Sample number.
- 5 N = No result returned in time for this registration\sample.
- 6 C = Corrected results will be accepted for non-analytical errors. Corrected results will be accepted up to 4 weeks after the final submission deadline, on application, with evidence of analysis. Late results are only accepted if there has been a Randox error.

 R = Incorrect results can be removed retrospectively on request.

TARGET SCORE CHART

The Target Score (TS) allows you to assess your performance at a glance. The TS relates the %Deviation of your result from the Mean to a Target Deviation for Performance Assessment (TDPA). TDPAs are set to encourage participants to achieve and maintain acceptable performance. TDPAs are fit-for-purpose performance criteria which are set taking guidance from ISO/IEC17043, ISO13528 and IUPAC. Target Deviations for Performance Assessment are also used to calculate the Standard Deviation for Performance Assessment (SDPA).



1 This is the upper deviation limit of performance for this parameter. TDPAs are reviewed regularly and deemed fit for purpose by the RIQAS Advisory Panel.

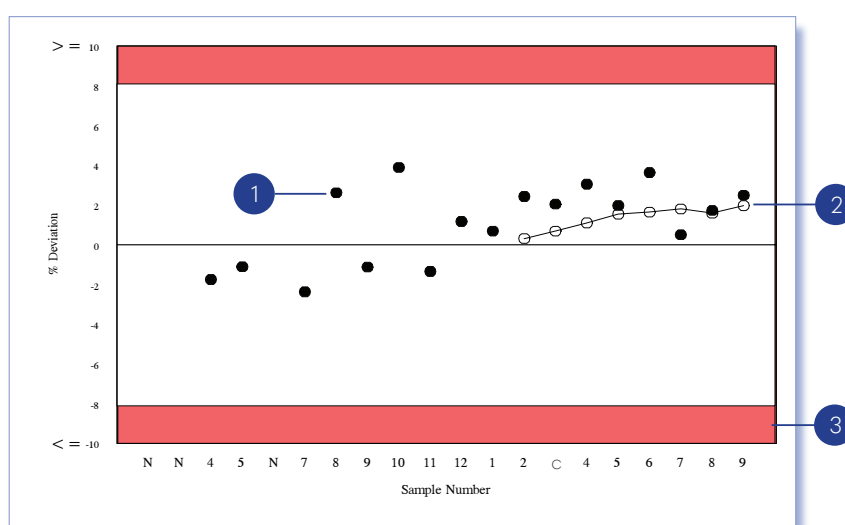
2 High scores ≥ 50 in the lighter shaded area represent acceptable, good or excellent performance.

3 Heavy shading for values 10 to 50 signifies poor performance.

%DEVIATION CHARTS

The %Deviation by sample chart helps to identify trends and shifts in performance.

$$\%Deviation = \frac{\text{Your Result} - \text{Consensus Mean}}{\text{Consensus Mean}} \times 100\%$$

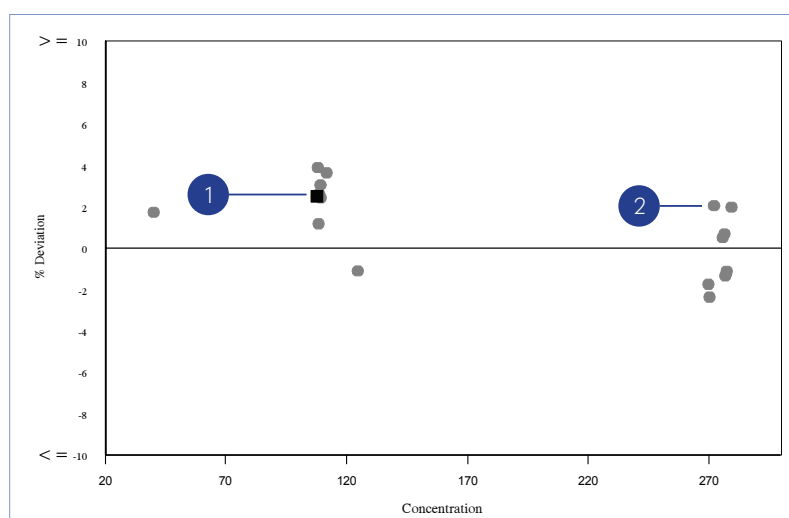


1 %Deviation from Mean for Comparison.

2 Plot of Running Mean %Deviations (average of the last 10 %Deviations for the sample indicated).

3 Acceptable limits of performance. These are defaulted to RIQAS TDPAs but can be set to e.g. biological variation or regulatory requirement on request.

The %Deviation by concentration chart enables rapid assessment of concentration related biases. Biases at low or high concentrations can be easily determined.



1 Current sample indicated by square.

2 %Deviation at specific concentration.

SUMMARY PAGE

Located at the back of the RIQAS Report, the Summary Page collates the key information, allowing participants to review the performance of all parameters at-a-glance.

Analyte	Mean for Comparison	Your Result	SDI	RMSDI	%DEV	RM%DEV	TS	RMTS	Performance
Albumin	2.120	2.230	1.00	0.37	5.2	2.0	72	107	
Alkaline Phosphatase	17.705	19.000	0.61	-0.27	7.3	-2.9	93	105	
ALT (GPT)	12.387	12.000	-0.33	-0.47	-3.1	-3.8	119	103	
Amylase, Total	20.454	22.000	0.72	-0.29	7.6	-2.5	86	103	
AST (GOT)	11.976	11.000	-0.86	-0.03	-8.2	-0.4	78	100	
Bicarbonate	8.203	6.900	-1.48	0.15	-15.9	1.5	54	98	
Bilirubin, Direct	0.251	0.380	<u>2.57</u>	2.64	<u>51.3</u>	47.2	<u>31</u>	29	▲
Bilirubin, Total	0.701	0.640	-0.91	-0.29	-8.8	-2.9	76	101	
Calcium	6.074	6.020	-0.19	-0.40	-0.9	-1.8	120	92	
Chloride	76.353	77.000	0.30	-0.28	0.8	-0.8	120	98	
Cholesterol	112.696	110.000	-0.55	0.05	<u>2.4</u>	0.2	97	115	
CK, Total	111.659	111.000	-0.08	0.35	-0.6	2.5	120	107	
Creatinine	0.607	0.620	0.27	0.06	2.1	0.5	120	117	
Glucose	36.429	36.000	-0.26	-0.84	-1.2	-3.7	120	82	
HDL-Cholesterol	98.836	102.000	0.21	-0.04	3.2	-0.4	120	113	
Iron	97.374	99.000	0.28	0.01	1.7	0.1	120	114	
Lactate		No Result		Too Few		Too Few	N/A	N/A	
LD (LDH)	85.894	87.000	0.11	-0.70	1.3	-6.3	120	89	
Magnesium	1.313	1.390	0.79	-0.07	5.8	-0.5	82	107	
Phosphate, Inorganic	1.451	1.540	1.02	0.02	6.1	0.1	71	112	
Potassium	1.770	1.840	1.10	-0.25	3.9	-0.7	67	99	
Protein, Total	3.850	3.830	-0.11	0.07	-0.5	0.3	120	114	
Sodium	112.537	114.000	0.58	-0.01	1.3	-0.0	95	104	
TIBC	133.143	133.000	-0.01	-0.01	-0.1	-0.1	120	117	
Trig Total	23.626	24.000	0.18	-0.09	1.6	-0.6	120	114	
Urea	5.872	5.000	<u>-2.02</u>	-0.57	<u>-14.9</u>	-4.0	<u>41</u>	95	▲
Uric Acid (Urate)	3.135	3.100	-0.20	-0.44	-1.1	-2.4	120	107	
			ORMSDI -0.05		ORM%DEV 0.8		ORMTS 102		

- Red triangle appears when all performance indicators (SDI, %DEV and TS) exceed acceptable performance, i.e: when
SDI >= 2
TS < 50
%DEV > acceptable limits set
- RMSDI - is the Running Mean of the 10 previous SDIs (if fewer than 10 results on file, "Too Few" is printed).
- RM %DEV - Average of the last 10 %DEV for this parameter.
- RMTS - Average of the last 10 Target Scores for this parameter.

- All poor performance is highlighted in bold and underlined.
- Overall RMSDI = average RMSDI for this sample distribution.
- Overall RM%DEV = average RM%DEV for this sample distribution.
- Overall RMTS = average RMTS for this sample distribution.

END-OF-CYCLE QUANTITATIVE REPORT

The End-of-Cycle Report is sent to labs receiving standard reports at the end of each cycle and provides a complete summary of statistics. Results can also be compared to the previous cycle.

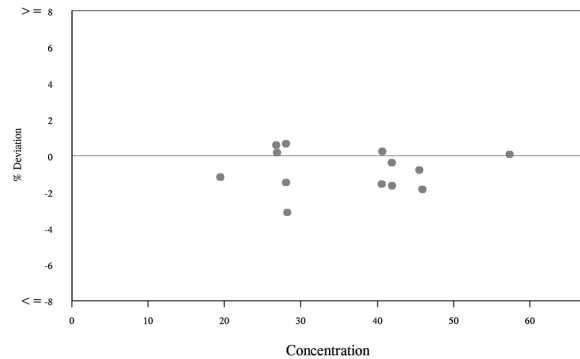
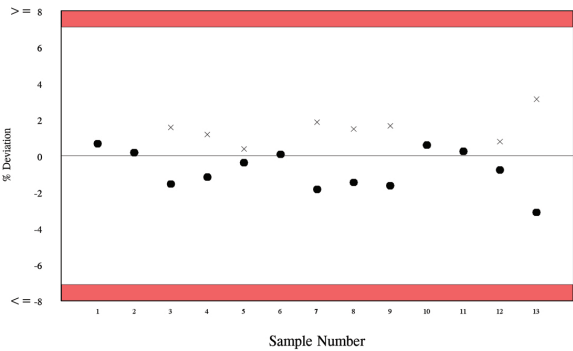
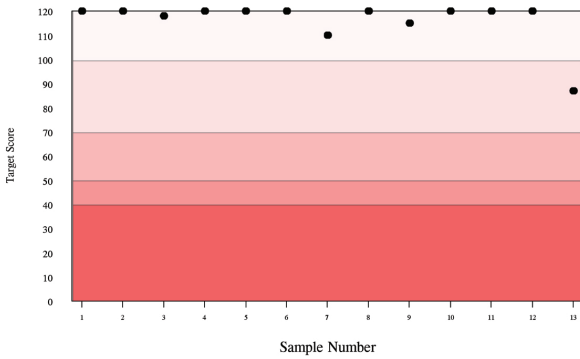
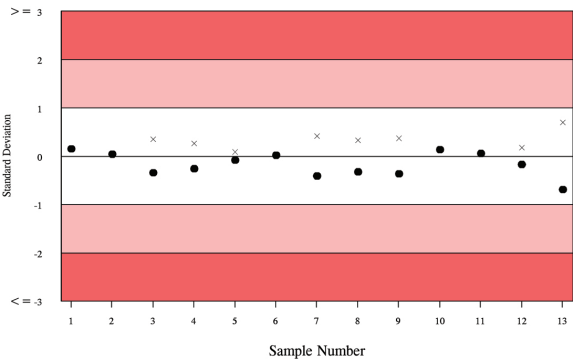
Albumin, g/l

Method: Bromocresol Purple
Instrument: Siemens/Dade Dimension RxL/Max/Xpand
Reagent: Siemens/Dade Behring

RIQAS TDPA: 7.1% **Biological Variation:** 3.9%

Sample	Result	Unit	N	Mean for Comparison	CV %	Um	SDPA	SDI	TS	%Deviation
1	28.200	g/l	68	I 28.013	2.4	0.10	1.26	0.15	120	0.67
2	26.900	g/l	87	I 26.853	2.7	0.10	1.21	0.04	120	0.17
3	39.900	g/l	71	I 40.531	2.5	0.15	1.82	-0.35	118	-1.56
4	19.200	g/l	81	I 19.429	2.5	0.07	0.87	-0.26	120	-1.18
5	41.700	g/l	67	I 41.859	2.0	0.13	1.88	-0.08	120	-0.38
6	57.300	g/l	87	I 57.257	2.7	0.21	2.58	0.02	120	0.08
7	45.000	g/l	72	I 45.850	2.1	0.14	2.06	-0.41	110	-1.85
8	27.600	g/l	87	I 28.013	2.5	0.09	1.26	-0.33	120	-1.47
9	41.200	g/l	70	I 41.891	2.2	0.14	1.88	-0.37	115	-1.65
10	26.900	g/l	83	I 26.742	3.3	0.12	1.20	0.13	120	0.59
11	40.700	g/l	71	I 40.601	2.2	0.14	1.83	0.05	120	0.24
12	45.100	g/l	80	I 45.456	2.2	0.14	2.04	-0.17	120	-0.78
13	27.300	g/l	63	I 28.179	2.0	0.09	1.27	-0.69	87	-3.12

	Cycle 45	Cycle 46
Cycle Average SDI	-0.23	-0.18
Cycle Average TS	110	116
Cycle Average %DEV	-1.05	-0.79
Cycle Average Absolute SDI	0.36	0.24
Cycle Average Absolute %DEV	1.63	1.06



END-OF-CYCLE REPORT TEXT SECTION

The text section summarises the statistical information for all samples.

1 Albumin, g/l

2 **Method:** Bromocresol Purple
Instrument: Siemens/Dade Dimension RxL/Max/Xpand
Reagent: Siemens/Dade Behring

3 **RIQAS TDPA:** 7.1% **Biological Variation:** 3.9%

Your assay details at the end of the cycle.
The RIQAS TDPA and biological variation
for the parameter are shown if available.

4	5	6	7	8	9	10	11	12	13	14
Sample	Result	Unit	N	Mean	SDPA	U _m	CV%	SDI	TS	% Deviation
1	28.200	g/l	68	I 28.013	1.26	0.10	2.4	0.15	120	0.7
2	26.900	g/l	87	I 26.853	1.21	0.10	2.7	0.04	120	0.2
3	39.900	g/l	71	M 40.531	1.82	0.15	2.5	-0.36	116	-1.5
4	19.200	g/l	81	I 19.429	0.87	0.07	2.5	-0.27	120	-1.2
5	41.700	g/l	67	I 41.942	1.88	0.13	2.0	-0.09	120	-0.4
6	57.300	g/l	87	I 57.257	2.58	0.21	2.7	0.02	120	0.1
7	45.000	g/l	72	I 45.850	2.06	0.14	2.1	-0.43	108	-1.8
8	27.600	g/l	87	I 28.011	1.26	0.09	2.5	-0.34	118	-1.5
9	41.200	g/l	70	I 41.823	1.88	0.14	2.2	-0.38	113	-1.6
10	26.900	g/l	83	I 26.742	1.20	0.12	3.3	0.14	120	0.6
11	40.700	g/l	71	I 40.601	1.83	0.13	2.2	0.06	120	0.2
12	45.100	g/l	80	I 45.119	2.05	0.14	2.2	-0.18	120	-0.8
13	27.300	g/l	63	I 28.454	1.27	0.09	2.0	-0.72	86	-3.1

Summary of your results and statistics are
shown, including Mean for Comparison,
SDPA, %CV, U_m, SDI, Target Score,
%Deviation.

	Cycle 45	Cycle 46
15 Cycle Average SDI	-0.23	-0.18
Cycle Average TS	110	116
Cycle Average %DEV	-1.05	-0.79
16 Cycle Average Absolute SDI	0.36	0.24
Cycle Average Absolute %DEV	1.63	1.06

Table containing a summary of your
performance for previous cycle and current
cycle, including Average Absolute SDIs and
%Deviations.

END-OF-CYCLE REPORT TEXT SECTION

- 1 Report presented in your chosen unit
- 2 Your assay details as of the last sample
- 3 RIQAS TDPA and Biological variation
- 4 Sample number
- 5 Your results for each sample
- 6 Unit your result was returned in
- 7 Number of results used for statistical analysis
- 8 Mean for Comparison (including comparison level)
- 9 SDPA = Standard Deviation for performance assessment
- 10 Uncertainty of Mean for Comparison
- 11 Coefficient of Variation (%)
- 12 Your Standard Deviation Index
- 13 Your Target Score
- 14 Your %Deviation

15 Cycle average of your performance indicators – Standard Deviation Index, Target Score and %Deviation.

Cycle Average SDI =
$$\frac{\text{(Sum of SDIs returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

Cycle Average Target Score =
$$\frac{\text{(Sum of your Target Scores returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

Cycle Average %Deviation =
$$\frac{\text{(Sum of your \%Deviations returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

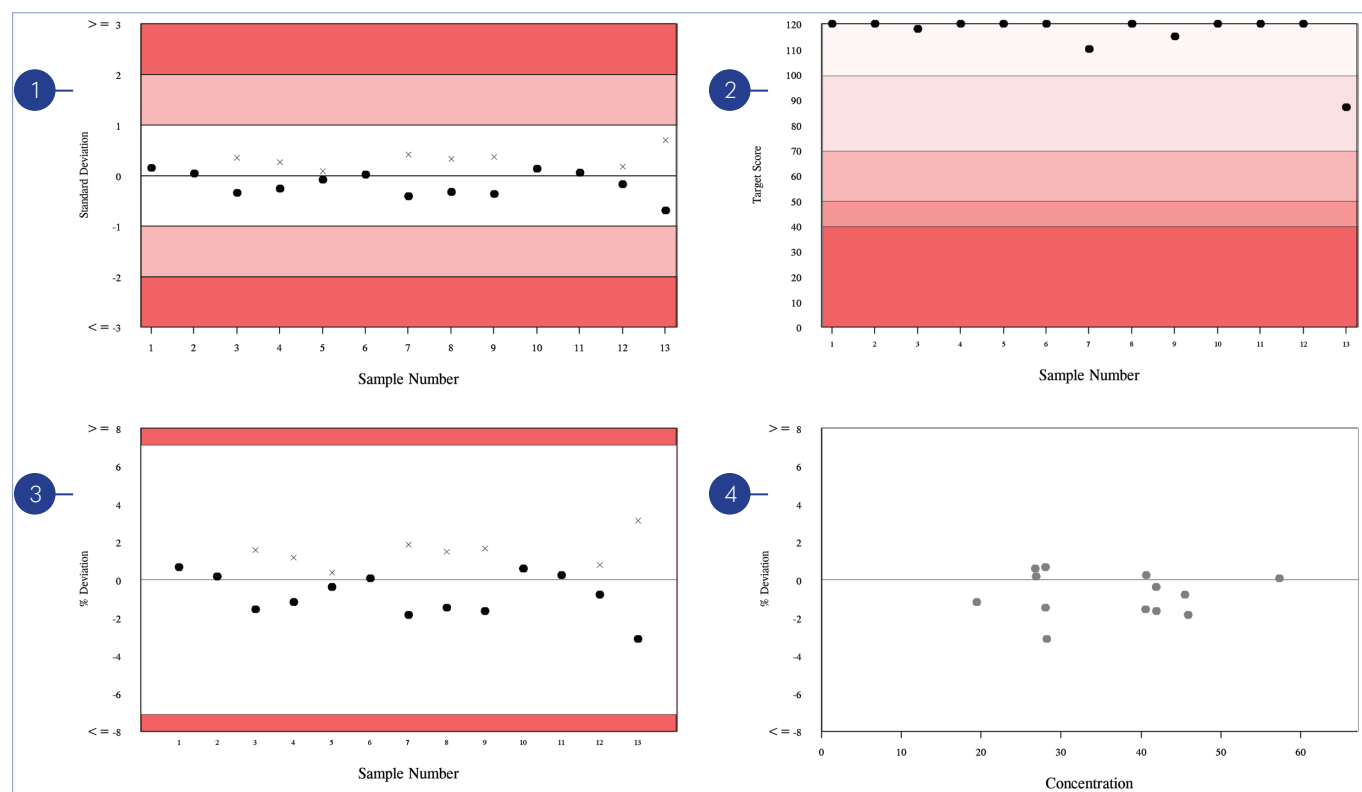
16 Cycle average for Absolute values of your SDI and %Deviation. Absolute values show how far a value is from zero regardless of the sign. This is an indication of the magnitude of accuracy.

Cycle Average Absolute SDI =
$$\frac{\text{(Sum of your Absolute SDIs returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

Cycle Average Absolute %Deviation =
$$\frac{\text{(Sum of your Absolute \%Deviations returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

END-OF-CYCLE CHART SECTION REPORT

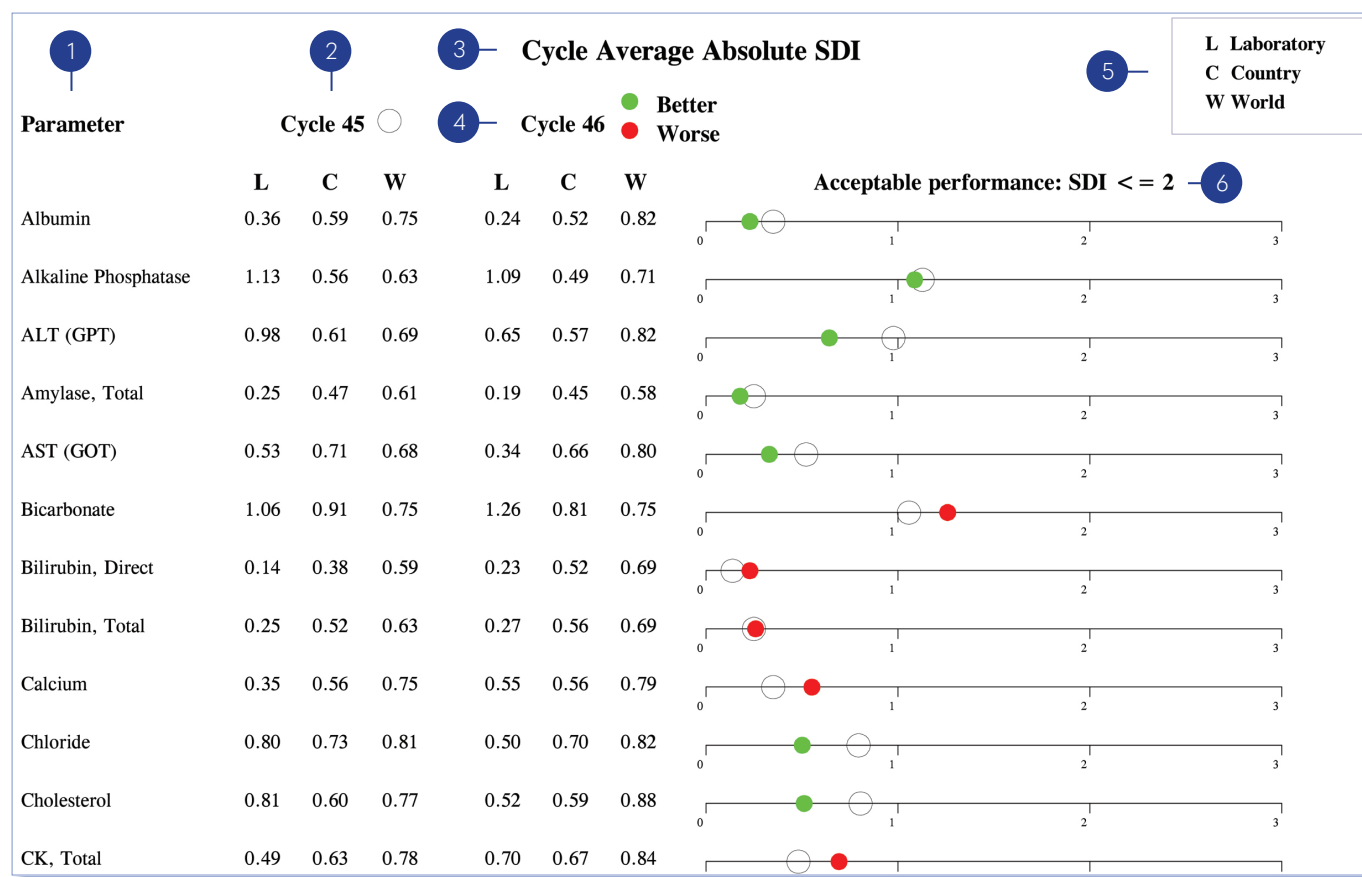
Your results for current cycle shown in various diagrams.



1	Levey-Jennings chart	Shows your SDIs for a full cycle. • Shows SDI (positive and negative) x Shows absolute SDI
2	Target Score chart	Shows your Target Scores for a full cycle.
3	%Deviation by sample chart	Shows your %Deviations for a full cycle. Acceptable limits equal to TDPA unless alternative limits are registered by the lab. • Shows %Deviation (positive and negative) x Shows absolute %Deviation
4	%Deviation by Concentration chart	Shows your results for a full cycle.

END-OF-CYCLE CURRENT & PREVIOUS CYCLE ABSOLUTE SDIs REPORT

Based on the cycle average absolute SDI, this chart provides a visual representation of your laboratory's performance compared to the previous cycle.



1	Parameter list	List of all parameters registered.
2	Results for previous cycle	Indicated by open circle on the chart.
3	Report title - Cycle Average Absolute SDI	This shows your performance this cycle compared to the previous cycle.
4	Results for current cycle	Indicated by a closed circle on the chart.
5	Legend	Cycle Average Absolute SDIs are shown for: L Your results throughout the cycle C All labs within your own country W All labs Worldwide
6	Graphical representation of Absolute SDIs	Acceptable performance is < 2. If Absolute SDI for current cycle is less than that for the previous cycle, this is indicated by a green circle. If Absolute SDI for current cycle is greater than that for the previous cycle, this is indicated by a red circle. The closer the circle is to zero, the better the performance.

END-OF-CYCLE CERTIFICATE OF PERFORMANCE REPORT

An End-of-Cycle report will be issued for all registrations. However, the Certificate of Performance will only be available for parameters where results for at least 50% of samples in the cycle have been returned. Labs joining after the beginning of the cycle will only receive the Certificate of Performance if they meet this criterion. Any parameters not included on the Certificate of Acceptable Performance will be listed on the Notification of Unacceptable Performance.

 RANDOX INTERNATIONAL QUALITY ASSESSMENT SCHEME

CERTIFICATE OF ACCEPTABLE PERFORMANCE

Laboratory Name

Laboratory Address

Country

1

2

LABORATORY REF. NO. III/A

3

CLINICAL CHEMISTRY - CYCLE 66

4

05/09/2022

This is to certify that the above participant took part in a cycle of external quality assessment and achieved an acceptable level of performance (Cycle Average Absolute SDI < 2) for the following parameters:

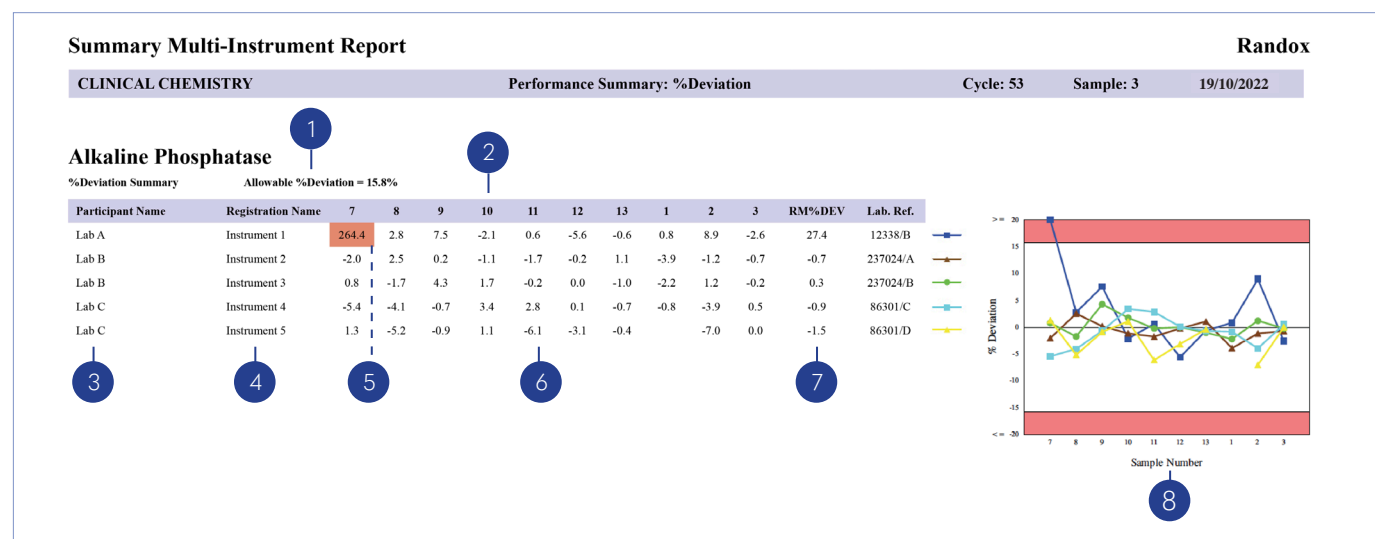
5

	6 Cycle Average Absolute SDI
Albumin - Bromocresol Green - Abbott Alinity i	1.61
Alkaline Phosphatase - AMP optimised to IFCC - Abbott Alinity c	0.80
ALT (GPT) - Tris buffer without P5P - Abbott Alinity c	1.20
Amylase, Total - Other 2-chloro-pNPG3 - Abbott Alinity c	0.99
AST (GOT) - Tris buffer without P5P - Abbott Alinity c	0.50
Bile Acids - Enzymatic Colorimetric - Abbott Alinity c	0.49
Bilirubin, Direct - Diazo with Dichloroaniline - Abbott Alinity c	0.36
Bilirubin, Total - Diazo with Dichloroaniline - Abbott Alinity c	0.72
Calcium - Arsenazo - Abbott Alinity c	0.69
Chloride - ISE, direct - Abbott Alinity c	1.08
Cholesterol - Cholesterol Oxidase - Abell Kendall - Abbott Alinity c	0.63
CK, Total - Abbott CK-NAC (IFCC) - Abbott Alinity c	0.47
Creatinine - Alkaline picrate no deproteinisation - Abbott Alinity c	1.42
GGT - Gamma glut.-3-carb.-4-nitro. - Abbott Alinity c	0.83
Glucose - Hexokinase - Abbott Alinity c	0.75

1	Full registration address	Your full registration address details.
2	Your lab reference number	Used to identify each lab.
3	Programme / cycle number	Programme and current, completed cycle number.
4	Date	Date End-of-Cycle report is issued.
5	Parameters	List of parameters including the assay details for which cycle absolute SDI is < 2.
6	Average Absolute SDI	Your Cycle Average Absolute SDI.

MULTI-INSTRUMENT REPORT

Register up to five instruments per programme at no extra cost. In addition to a standard report for each instrument, a multi-instrument report is also provided allowing comparative performance assessment.



- | | |
|---|---|
| <p>1 Allowable %deviation for the parameter in question, based on the RIQAS TDPA.</p> <p>2 Sample number.</p> <p>3 Lab name.</p> <p>4 Unique instrument ID.</p> | <p>5 Poor performance.</p> <p>6 %Deviation for each individual sample.</p> <p>7 RM %Dev - Average of the last 10 %Dev for this parameter.</p> <p>8 %Deviation chart comparing the performance of each instrument.</p> |
|---|---|

URINE TOXICOLOGY REPORT

Laboratory performance is presented in both quantitative and qualitative screening formats, allowing for easy interpretation at-a-glance.

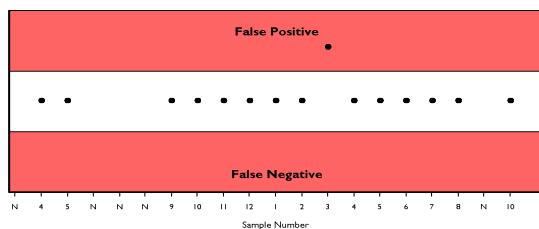
Screening Section

Quantitative Section

Amphetamines Group, ng/ml

Your Result Positive

Based on comparison value of 750
and your chosen cut-off value of 500
the correct response was Positive



MDMA 750 ng/ml
Ethanol 62.5 mg/dl
EDDP 75 ng/ml
Free Morphine 1500 ng/ml
Nortriptyline 375 ng/ml

	Cut-off	TN	TP	FN	FP	RC	NT	Total
Your Result	500	0	1	0	0	0	0	1
KIMS	500	0	21	0	0	0	0	21
	1000	0	0	0	9	0	0	9
	All	0	21	0	9	0	0	30
All Methods	150	0	1	0	0	0	0	1
	300	0	5	9	0	0	0	14
	500	0	32	49	0	0	0	81
	1000	65	0	0	10	0	3	78
	All	65	38	58	10	0	3	174
Competitive Antibody Binding	500	0	3	0	0	0	0	3
CEDIA	500	0	2	4	0	0	0	6
DRI-EIA	500	0	3	3	0	0	0	6
ELISA	500	0	0	1	0	0	0	1
EMIT	500	0	1	27	0	0	0	28
EMIT II+	500	0	0	8	0	0	0	8
Point of Care	500	0	0	5	0	0	0	5
Quidel Triage	500	0	2	1	0	0	0	3

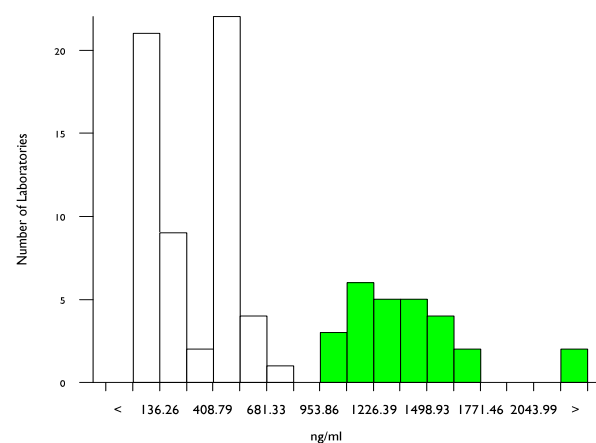
Performance History

Your Data (Last 10 Samples)	Your Method (This Sample)	Your Method (Last 10 Samples)	All Methods (This Sample)	All Methods (Last 10 Samples)
0 % False Negatives	0 % False Negatives	1 % False Negatives	34 % False Negatives	11 % False Negatives
10 % False Positives	30 % False Positives	11 % False Positives	6 % False Positives	5 % False Positives
90 % Correct Responses	70 % Correct Responses	88 % Correct Responses	60 % Correct Responses	83 % Correct Responses

	N	Mean	CV%	U _m	SDPA	Exc.
All Methods	74	656.297	77.4	73.82	507.99	23
KIMS	25	1344.540	15.1	50.82	203.30	2

▲ Your Result 1405.000 SDI 0.30
RMSDI -0.12

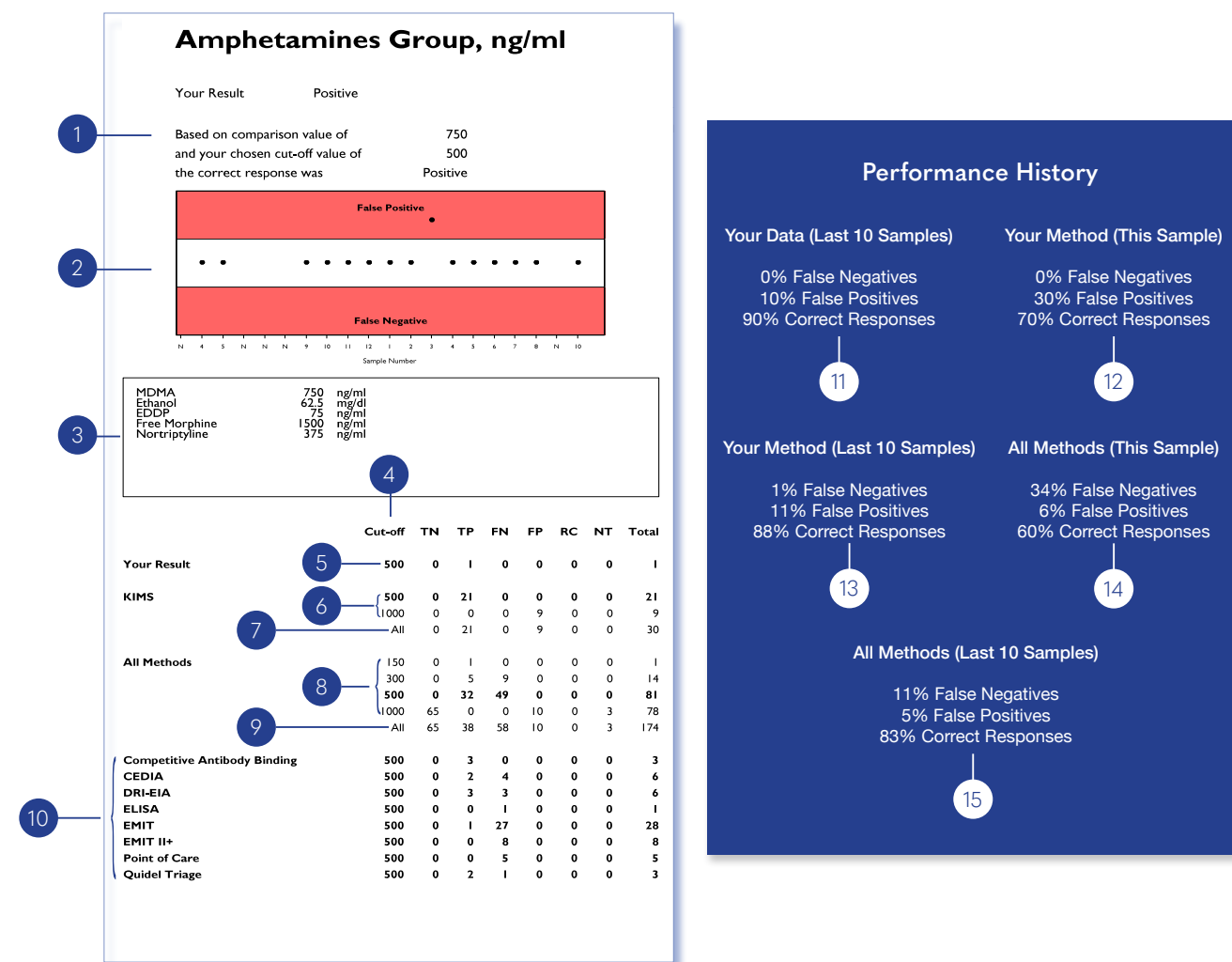
■ Mean for Comparison 1344.540



Method	N	Mean	CV%	U _m
EMIT	15	135.267	19.2	8.37
KIMS	25	1344.540	15.1	50.82
DRI-EIA	10	511.420	5.6	11.22
EMIT II+	5	119.540	22.4	14.98
CEDIA	5	298.942	89.9	150.22
Competitive Antibody Binding	4	540.725	2.7	9.19
ELISA	3	501.033	4.9	17.73

URINE TOXICOLOGY REPORT SCREENING SECTION

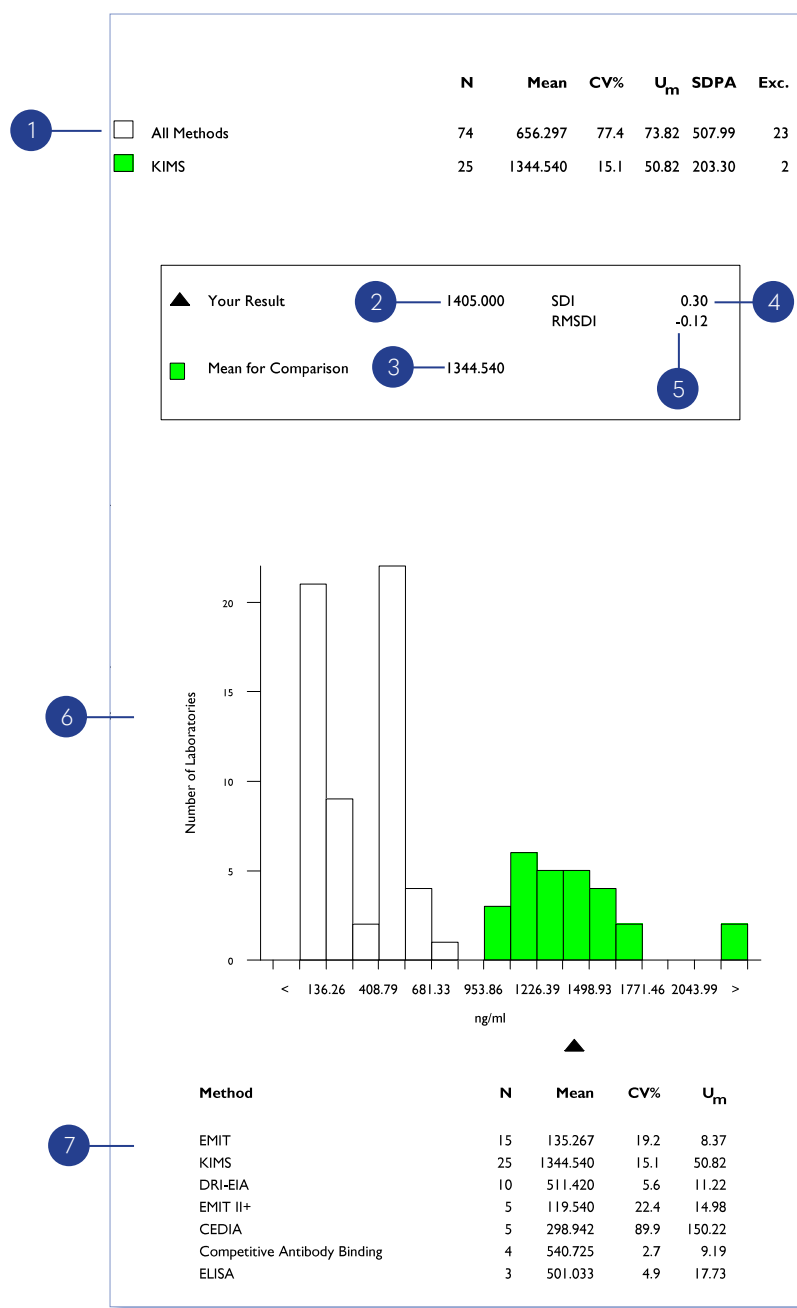
Qualitative comparison of screening results available for each parameter.



- Text section shows the correct response for the lab based on a comparison between the comparison value and the lab's cut off value.
- Screening Results:** This chart is a quick visualisation of your performance over the last 20 samples. A result in the white section indicates a correct response. A result in the upper red section indicates a False Positive response, and a result in the lower red section indicates a False Negative response.
- Comment section for RIQAS to provide your laboratory with additional relevant information regarding this sample, such as spiked metabolite concentration.
- Screening result response categories. All abbreviations indicated at the bottom of the report page.
Key
TN - true negative TP - true positive FN - false negative
FP - false positive RC - sent for confirmation NT - not tested
- Screening Summary:** Your screening result shown in the appropriate response category and your cut off for this sample.
- Screening results for all cut-offs returned for this sample within your method group.
- Total screening results over all cut-offs for your laboratory's method.
- Screening results for all cut-offs returned for this sample over all methods.
- Total screening results over all cut-offs for all methods.
- Screening results for other methods using same cut-off as your laboratory.
- Performance history for this parameter, based on previous 10 samples.
- Performance of your method over all cut-offs for this sample.
- Performance history of your method over all cut-offs, based on the previous 10 samples.
- Performance of all methods over all cut-offs for this sample.
- Performance history of all methods over all cut-offs, based on the previous 10 samples.

URINE TOXICOLOGY REPORT QUANTITATIVE SECTION

Quantitative statistical comparison available for each parameter.



1 **Quantitative Text Section:** Comparison statistics. Caution is needed when the N value is too small to support statistical significance.

2 Your Result.

3 Your Mean for Comparison.

4 **Standard Deviation Index** =

$$\frac{\text{Your Result} - \text{Mean for Comparison}}{\text{SD of Mean for comparison}}$$

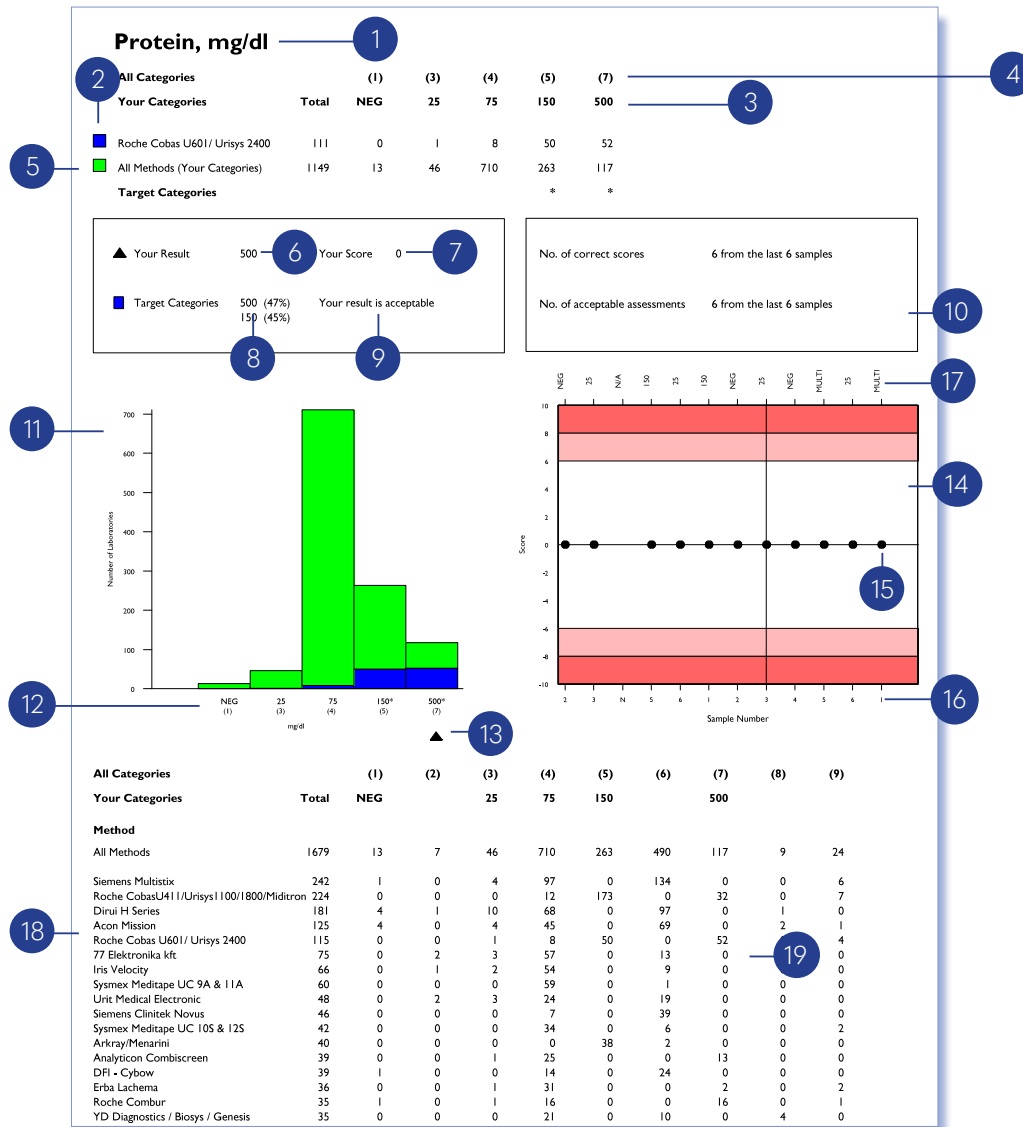
5 Running mean SDI = average of last 10 SDIs for this parameter (If fewer than 10 results, "Too Few" is printed).

6 **Quantitative Results Histogram:** This graph provides a quick visualisation of how your quantitative result falls into the overall picture for all methods and your method group.

7 All available method statistics for this sample.

URINALYSIS REPORT

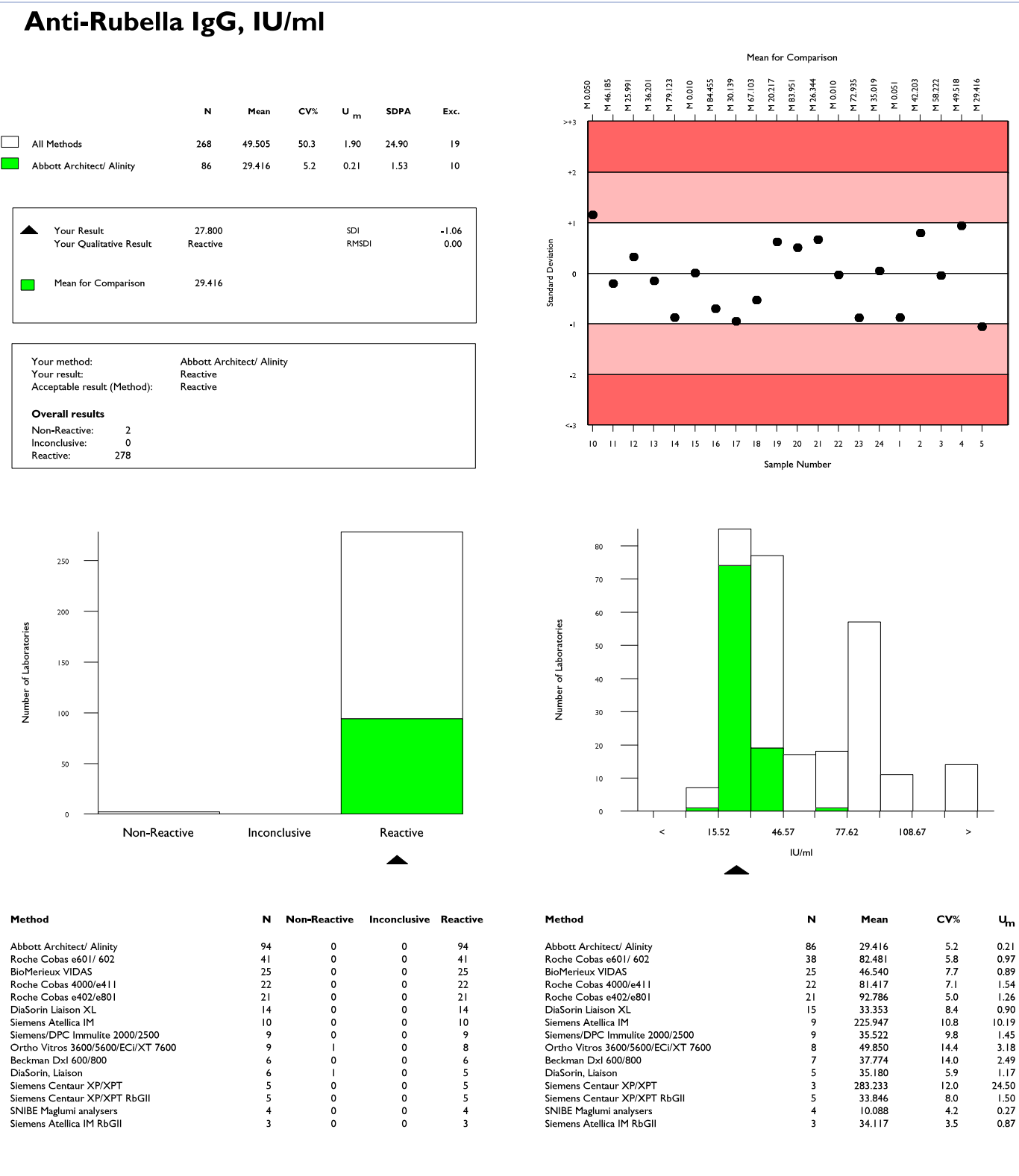
Your performance for each parameter is presented in a simple, convenient report.



- Categories are stated in your unit.
- Your method group.
- Your categories (available result options for chosen test strip and unit).
- All categories (result options) available for this parameter for any method (test strip).
- Results from all methods (test strips) returning results in the same categories as your lab.
- Your Result.
- Your Score:** Scores between 0-6 are acceptable, 7 borderline and 8-10 unacceptable.
- Target categories and percentages of submitted results in that categories. Target categories are based on 80% consensus in the results in your categories. Multiple categories may be used to make up the 80% consensus. Target categories are highlighted by * in text section.
- Performance Statement.
- Historical Performance:** Provides number of correct scores and acceptable assessments for the last 6 samples.
- Categories Histogram:** A quick visualisation of how your lab's result falls into the overall picture for your categories.
- Possible reporting categories for your method. Target categories are highlighted by *.
- Your result is indicated by the black triangle.
- Levey-Jennings type chart:** Acceptable scores (0-6) have no shading, borderline scores (7) have light red shading, unacceptable scores (8-10) have dark red shading.
- Score for each sample number.
- Sample Number.
- Target Categories:** If there was more than 1 target category assigned for a sample Multi is stated.
- All methods reported for this parameter.
- Detailed summary of results:** This table enables you to see how you compare to all other results.

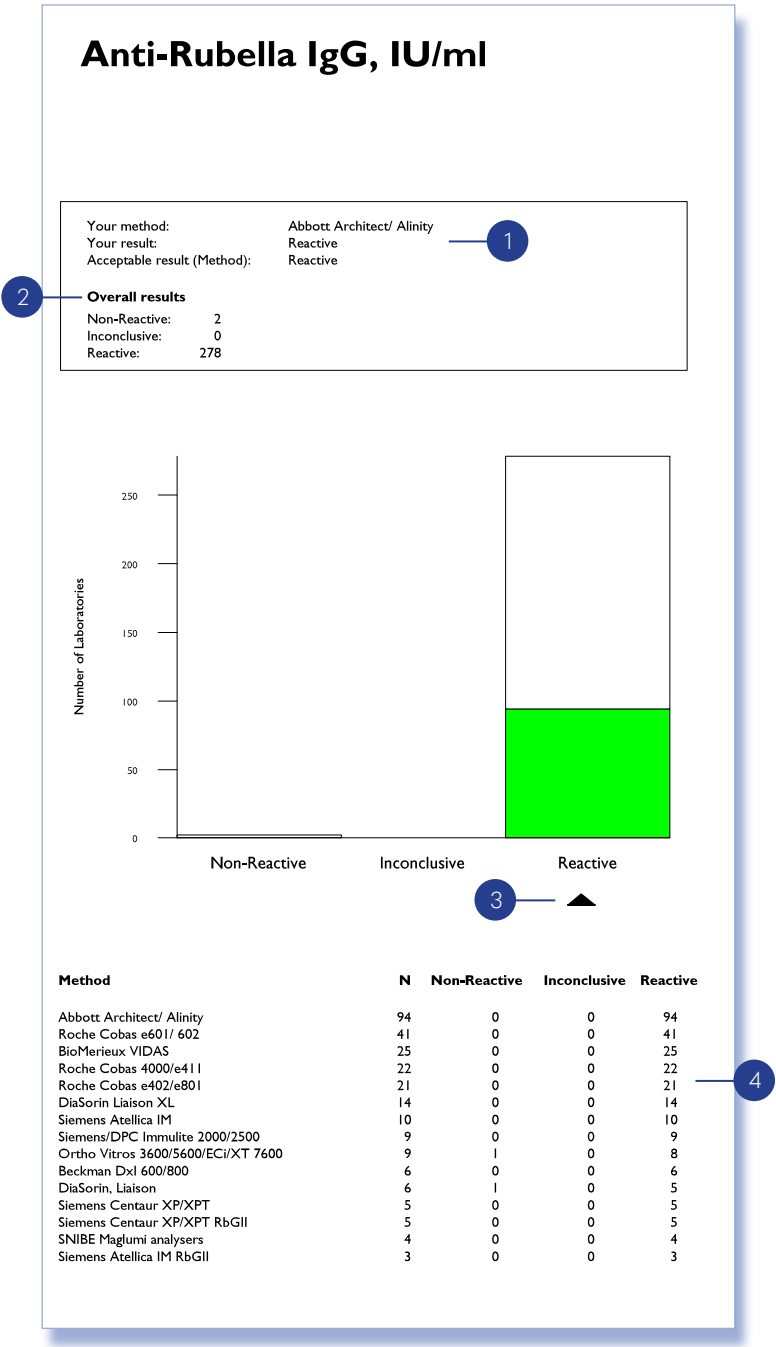
SEROLOGY REPORT

Laboratory performance is presented in both quantitative and qualitative screening formats, allowing for easy interpretation at-a-glance.



SEROLOGY: QUALITATIVE REPORT

Your performance for each sample is presented in a convenient single page per parameter report format.



- 1 Your qualitative result and chosen method are presented along with the acceptable result based on an 80% consensus. This consensus will be at the method level if there are ≥ 5 labs in the group or if there are < 5 labs, will be at the all method level.
- 2 Overall Summary shows the number of results for this parameter and sample which are non-reactive, inconclusive or reactive.

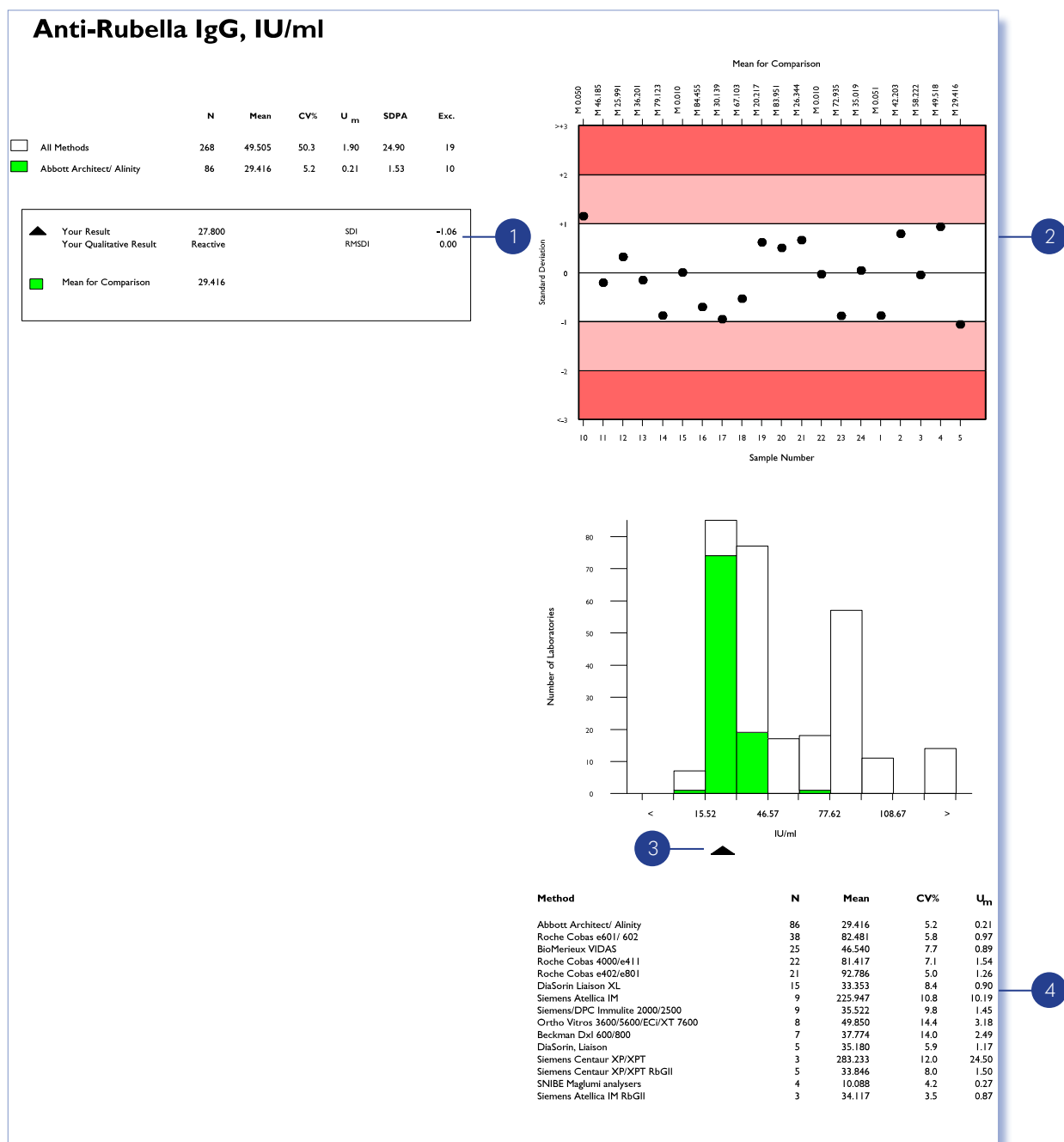
- 3 Your Result is shown as a black triangle on the category chart compared to other laboratories in groups:

All Methods

Your Method
- 4 Summary shows performance of all the methods used to analyse the parameter.

SEROLOGY: SCREENING (QUANTITATIVE) REPORT

Your performance for each sample is presented in a convenient single page per parameter report format.



1 Quantitative statistics for All Methods and Your Method are presented in your chosen unit along with your result and your performance scores (SDI and RMSDI).

2 **Levey-Jennings chart** - Your SDIs for previous 20 samples.

3 Your result is presented on the bar graph as a black triangle, showing how you compare to:

All Methods Your Method

4 Multi Method Statistics section provides an easy way of assessing the performance of the methods used to analyse the parameter.

SERUM INDICES: SUMMARY PAGE

The RIQAS Serum Indices EQA programme is designed for the pre-analytical assessment of Haemolytic, Icteric and Lipemic (HIL) interferences. HIL parameters include the option of quantitative or semi-quantitative reporting. Interpretation of chemistry parameter results is also included for a number of parameters. The summary page collates the key information on both the quantitative and qualitative results for the HIL parameters.

Sample 1 - Normal Sample 2 - Haemolytic Sample 3 - Lipaemic					
Sample	Analyte	Mean for Comparison	Your Result	SDI	%DEV
1	Haemolytic Index	13.750	14.000	0.02	1.8
	Icteric Index	0.980	1.100	0.17	12.2
	Lipaemic Index	13.600	8.000	-0.83	-41.2
2	Haemolytic Index	469.000	500.000	0.34	6.6
	Icteric Index	2.475	<2.500		
	Lipaemic Index	40.000	45.000	1.23	12.5
3	Haemolytic Index	53.000	<50.000		
	Icteric Index	5.700	6.100	0.28	7.0
	Lipaemic Index	42.000	<40.000		

Sample	Analyte	Target Categories	Your Result	Your Score
1	Haemolytic Index	0	0	0
	Icteric Index	0	0	0
	Lipaemic Index	0	0	0
2	Haemolytic Index	4+ 5+	5+	0
	Icteric Index	0	0	0
	Lipaemic Index	0	1+	1
3	Haemolytic Index	0	0	0
	Icteric Index	2+	2+	0
	Lipaemic Index	0	0	0

1 The first section shows the status of each of the samples i.e. if the sample is a normal sample or if it is haemolytic, icteric or lipaemic.

2 The next section shows the summary of the quantitative results for the Serum Indices and your performance (SDI and %DEV) for each sample.

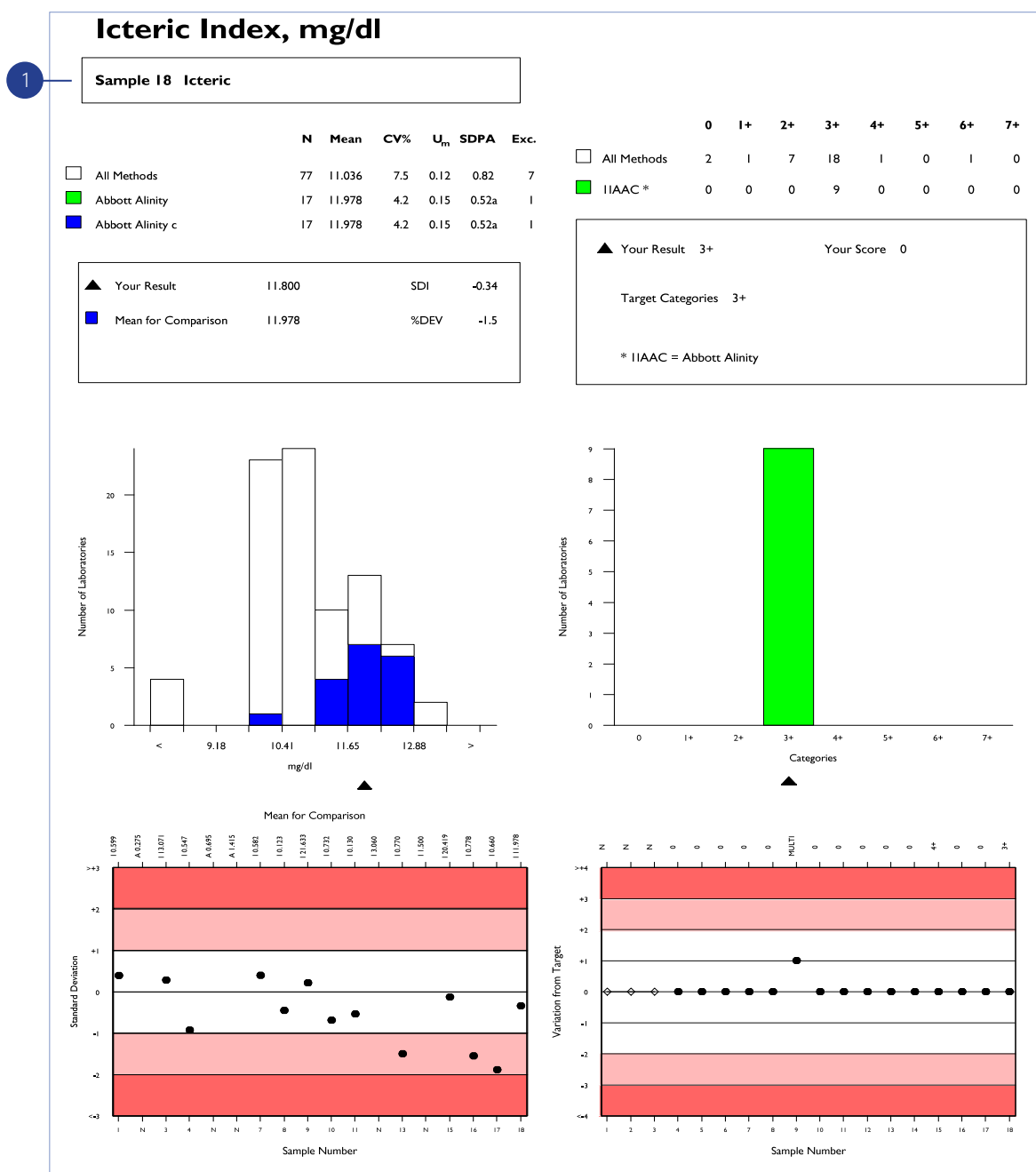
3 The final section shows the summary of the semi-quantitative results for the Serum Indices. This includes the target categories based off an 80% consensus in the results, your result and your score for each of the samples.

SERUM INDICES REPORT

The summary section is followed by report pages for the 3 serum indices parameters. There will be 3 pages for each index – one for each sample.

Quantitative Section

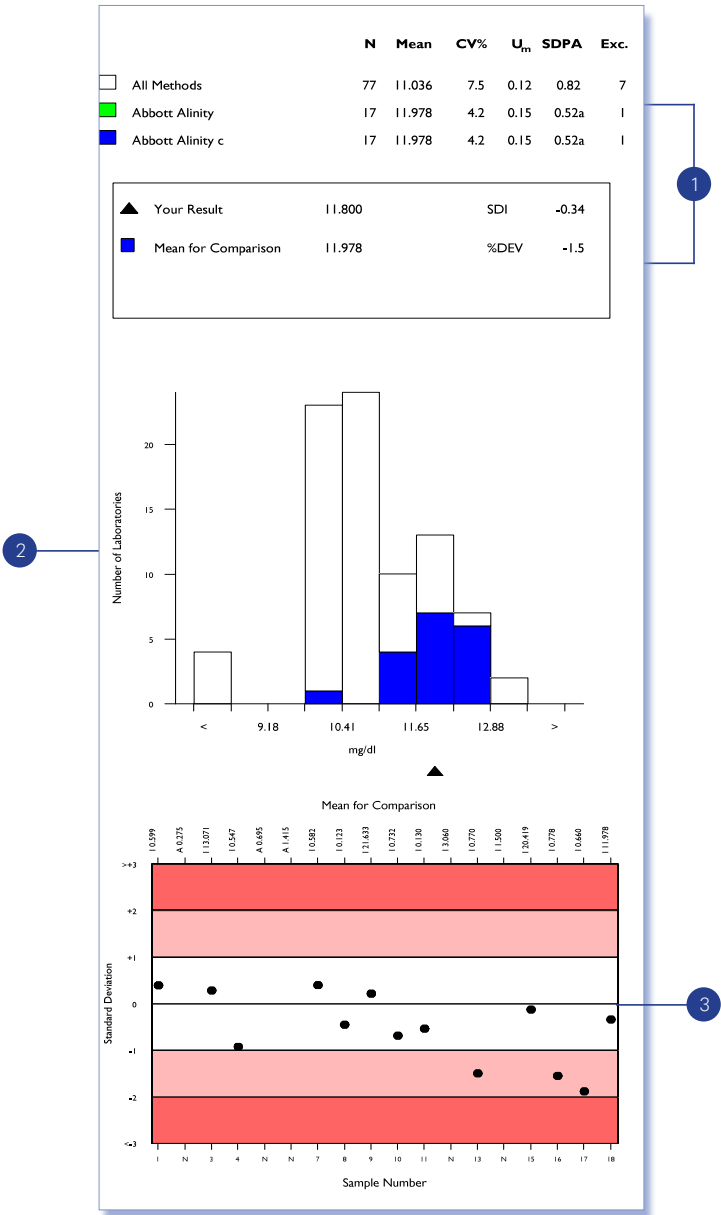
Semi-quantitative Section



Under the Serum Index parameter name the report will display the sample status e.g. if the sample should be flagging as haemolytic, icteric or lipaemic. As with all reports, the results contained within the report pages will be in the unit selected by the lab during the registration process.

SERUM INDICES REPORT: QUANTITATIVE SECTION

Quantitative comparison of results available for each index.



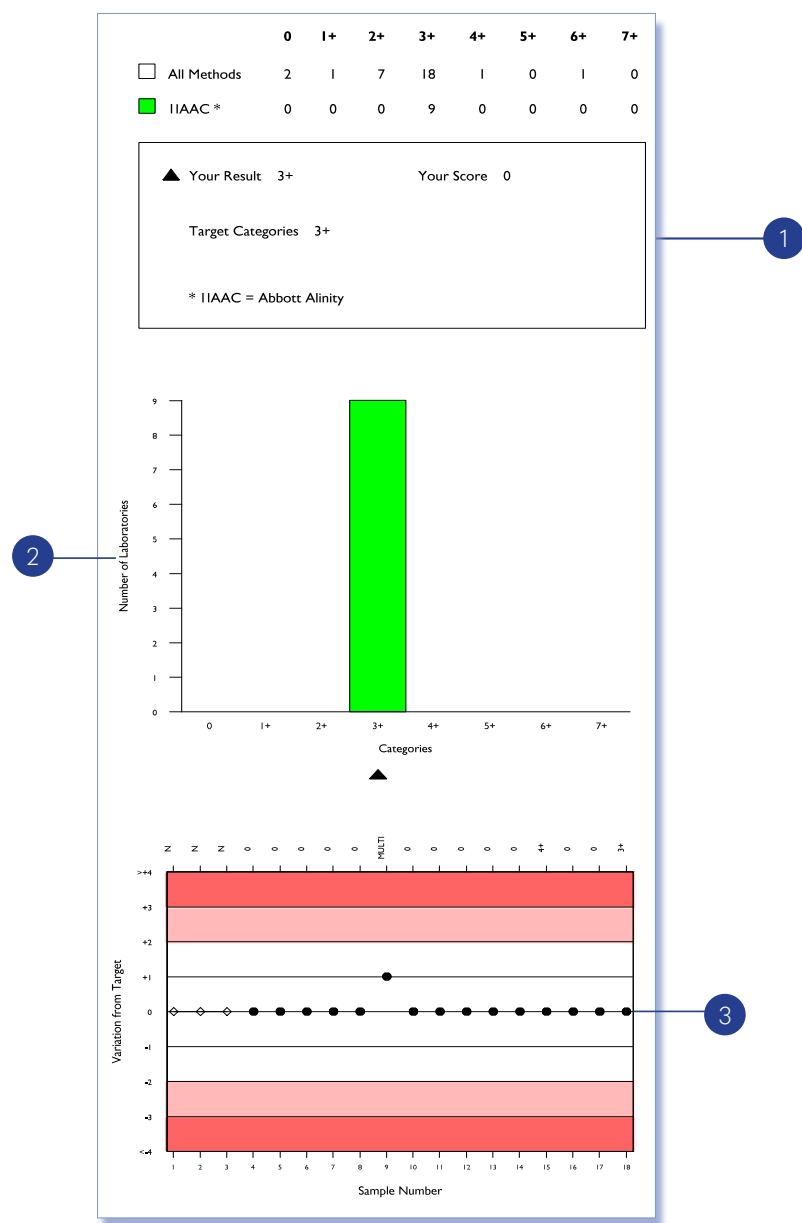
1 Text Section: In the text section you will see the All method, method and instrument means for comparison in addition to the respective statistics. Below this you will see your result, your Mean for comparison and your performance (SDI and %DEV) for this specific sample. For samples which do not hit specific flags for the indices, a large proportion of analysers will have a less than (<) setting. On a RIQAS report these will be counted in the excluded column. As one sample in each distribution will be a normal sample, it is likely there will be a large number of (<) results returned for these samples so we are indicating in this section the percentage of results that have been returned as a < or > result to allow labs to see if the number of excluded results is high that there is an explanation for this.

2 Histogram: As with other RIQAS reports, this histogram shows an overview of the spread of the results that have been returned for each level of comparison (all method (white), method (green) and instrument (blue)). The lab's result is indicated by the black triangle at the bottom of the chart.

3 Levey Jennings style chart: The Levey Jennings chart will display the lab's SDIs. These reflect laboratory performance in relation to SDPAs and are useful to monitor performance over time. Acceptable performance is SDI < 2. The sample numbers will be displayed along the bottom of the chart and the Means for Comparison including the level will be displayed along the top of the report.

SERUM INDICES REPORT: SEMI-QUANTITATIVE SECTION

Semi-quantitative comparison of the results available for each parameter.



1 Text Section: This shows the breakdown of the semi-quantitative results returned – broken down by all methods and the labs chosen method. The method is displayed as a code, the description for which is found in the box just below containing the lab's result.

The lab's result, target categories (based on an 80% consensus), and the lab's score based on how many categories away from the target category the result is, are displayed below the breakdown of each category.

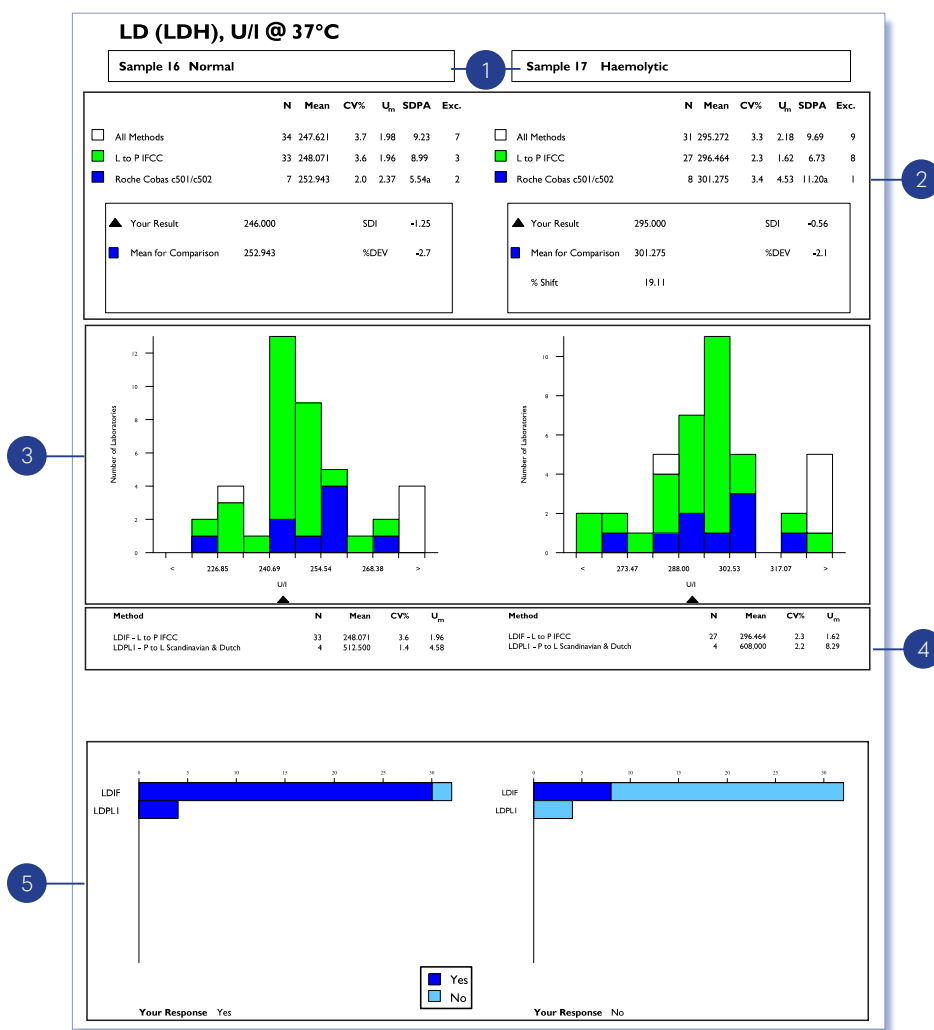
2 Histogram: The histogram shows a pictorial breakdown of the results returned for each category. The lab's result is indicated by the black triangle at the bottom of the chart.

3 Levey Jennings chart: This chart will display the lab's score or variation from the target category.

The sample numbers will be displayed along the bottom of the chart and the target categories along the top. If there is more than one target category, the chart will display the word 'Multi'.

SERUM INDICES REPORT: CHEMISTRY PARAMETER PAGE

Following the report pages for the 3 Serum Indices, there are the report pages for any chemistry parameters labs have registered for. There are 2 pages for each parameter, one showing the comparison between the first sample (the normal sample) and the second sample and the second page showing the comparison between the first and third sample respectively.



1 Sample Status: Under the chemistry parameter name the report will display the sample status e.g. if the sample should be flagging as haemolytic, icteric or lipaemic for the 2 samples being compared. As with all reports, the results contained within the report pages will be in the unit selected by the lab during the registration process.

The rest of the report page shows the same information for each of the 2 samples being compared.

The first sample of the 3 in each distribution will be the normal sample, the other 2 may or may not flag for one or more of the Indices.

2 Text Section: In the text section you will see the all method, method and instrument means for comparison and the respective statistics. Below this you will see your result, your Mean for comparison and your performance (SDI and %DEV) for this specific sample.

The % shift in the Means for Comparison between the normal and the affected sample is displayed in the results box for the second and third sample.

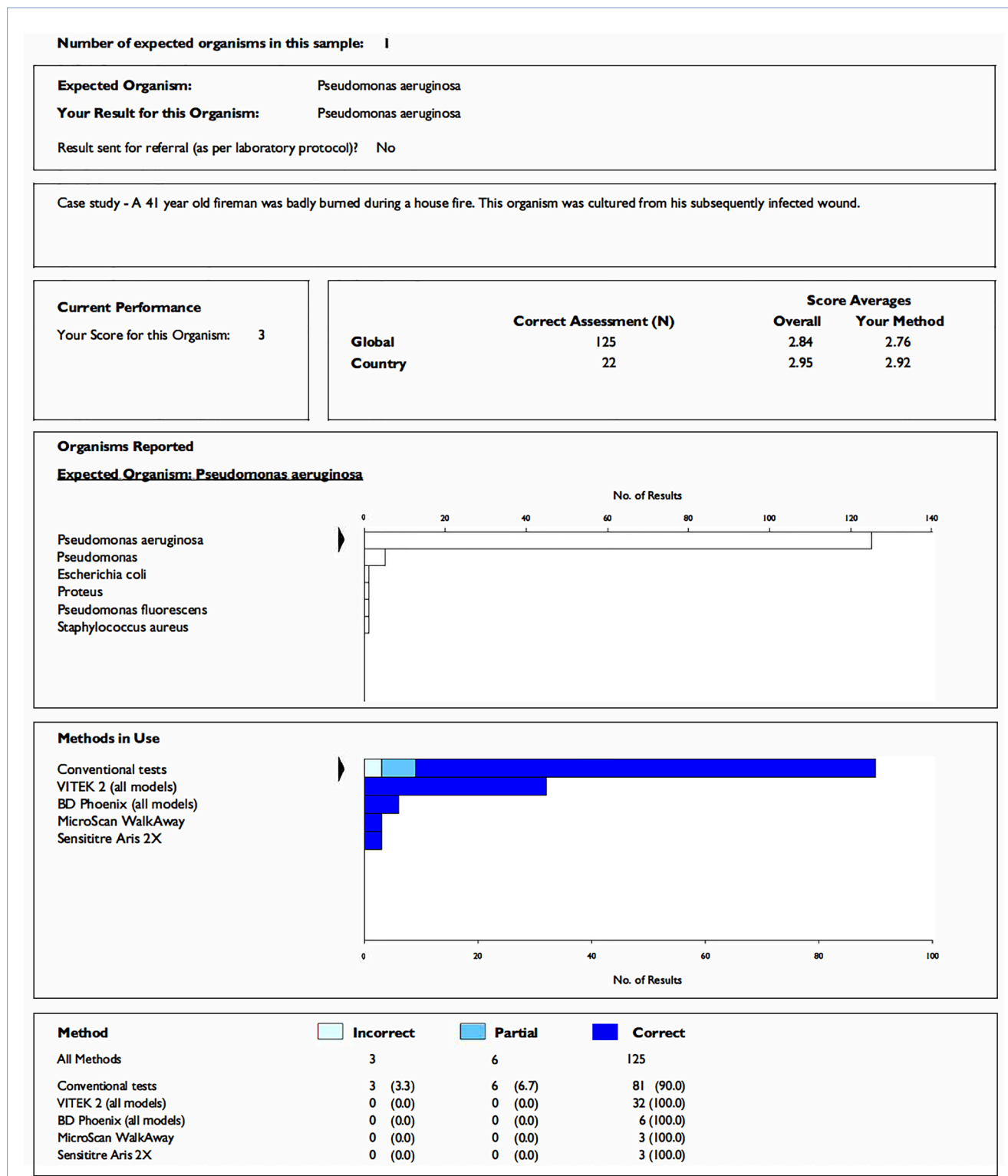
3 Histogram: As with other RIQAS reports, this histogram shows an overview of the spread of the results that have been returned for each level of comparison (all method (white), method (green) and instrument (blue)). The lab's result is indicated by the black triangle at the bottom of the chart.

4 Method Summary Section: As with other RIQAS reports, this section provides an easy way of assessing the performance of other methods used to analyse the parameter in question. The code at the beginning of the description is the key to the following section - Reporting of the Result based on Serum Indices flag.

5 Reporting of the Result based on Serum Indices flag: Depending on the Index that has been flagged, the lab may choose to not report the result to the clinician. In this section the lab can report on whether they would report the result for this parameter based on the result from the Serum Indices analysis.

BACTERIAL IDENTIFICATION REPORT

Presented in a convenient single report, all results for the current sample will be displayed within 6 sections.



BACTERIAL IDENTIFICATION REPORT

Participants can quickly and easily identify their performance for the current sample against their peers across geographic locations and those utilising same methodologies. Each section is explained in further detail below.

1

Number of expected organisms in this sample: 1

Expected Organism:	Pseudomonas aeruginosa
Your Result for this Organism:	Pseudomonas aeruginosa
Result sent for referral (as per laboratory protocol)?	No

Case study - A 41 year old fireman was badly burned during a house fire. This organism was cultured from his subsequently infected wound.

Current Performance Your Score for this Organism: 3	Score Averages		
		Overall	Your Method
	Global	125	2.84
	Country	22	2.95

3

2

1 Sample Results: This shows the expected organism, the labs selected organism and information on the laboratory protocol being followed. Information on the lab's protocol will have an effect on the scoring for this sample.

2 Case Study: Clinical details are provided for each sample.

3 Performance Scoring: This will contain the lab's specific score for this sample. It will also show the correct assessments and overall scoring with the lab's country and globally.

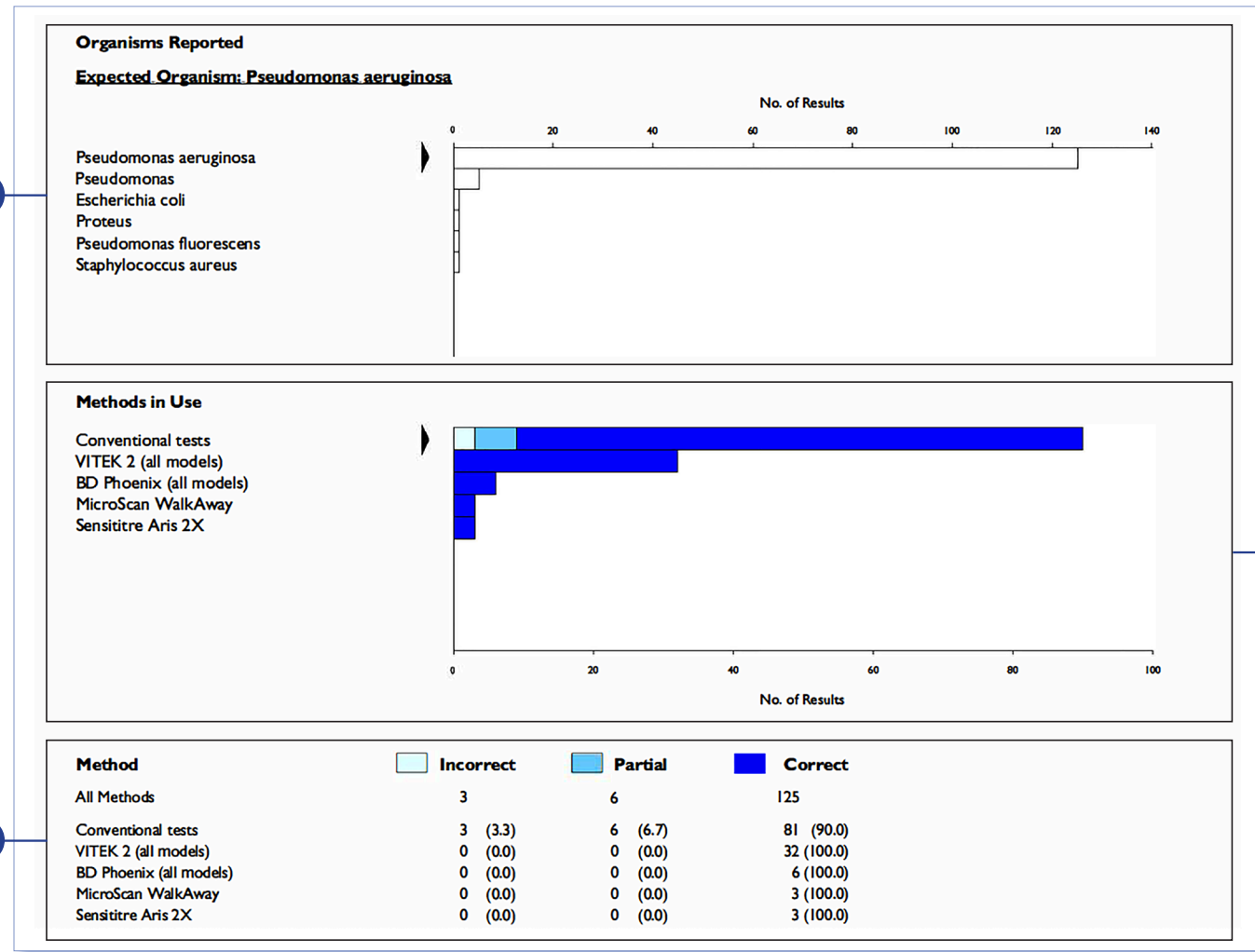
If sample is NOT sent for referral, scoring is marked out of 3

- Correct Genus + species = 3
- Correct Genus + species is blank, if this is lab protocol = 3
- Correct Genus + species is blank = 1
- Correct Genus + incorrect species = 1
- Incorrect Genus and species but correct Gram stain = 0
- Incorrect Genus, species and Gram stain = -1

If sample is sent for referral, scoring is marked out of 2

- Correct Genus + species = 2
- Correct Genus + species is blank, if this is lab protocol = 2
- Correct Genus + species is blank = 1
- Correct Genus + incorrect species = 1
- Incorrect Genus and species but correct Gram stain = 0
- Incorrect Genus, species and Gram stain = 0

BACTERIAL IDENTIFICATION REPORT



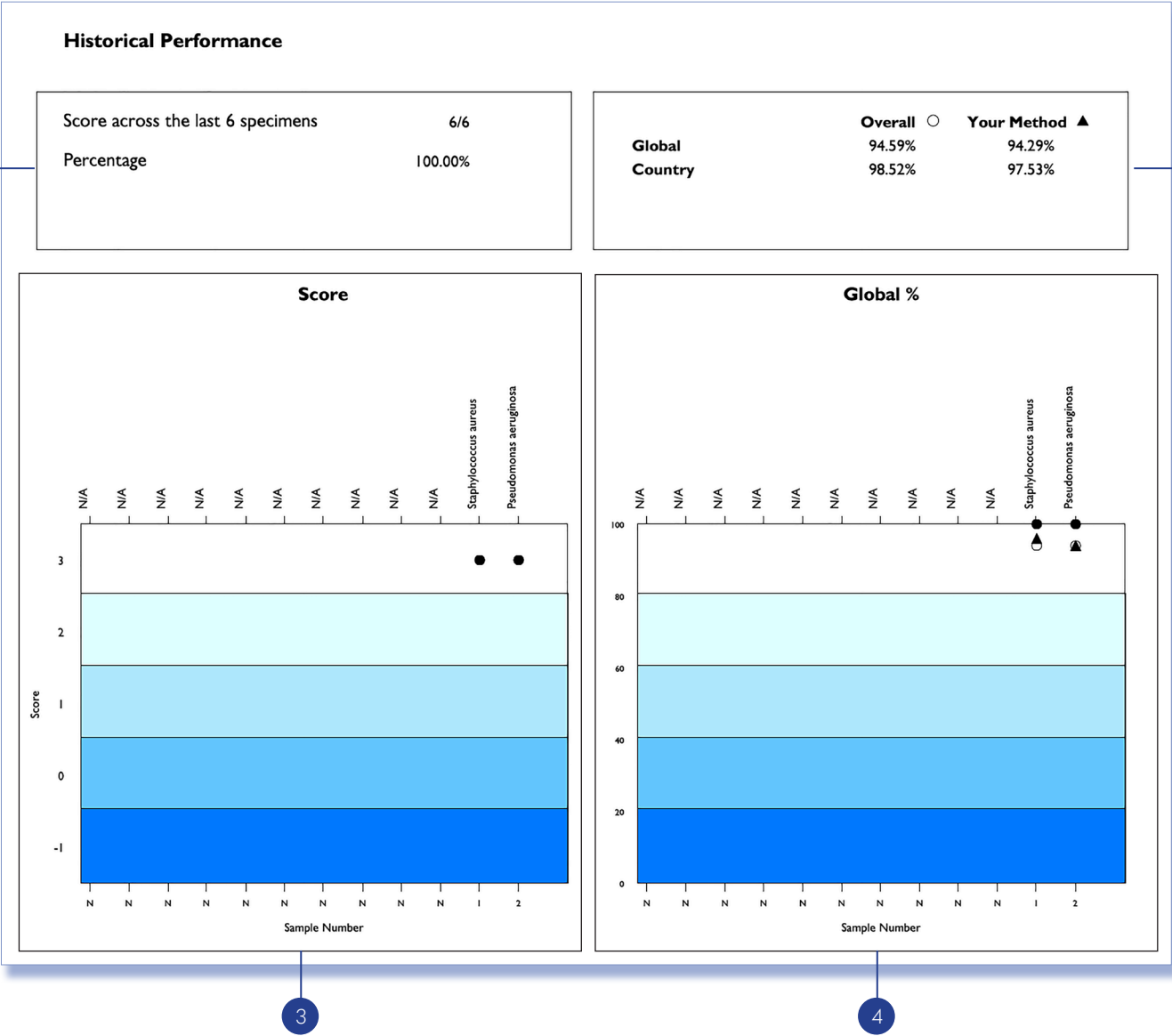
4 **Bar Chart of Organisms Reported:** This will list all organisms reported by each lab ordered in descending frequency. The black triangle indicates the lab's result.

5 **Bar Chart Detailing Methods Used:** This will list all methods used by each lab ordered in descending frequency. The bars are colour coded to highlight correct, partial and incorrect responses for each method. The black triangle indicates the lab's result.

6 **Method Summary Section:** This is a table providing the number of responses by method. The figures in brackets indicate the percentage of responses for each method.

BACTERIAL IDENTIFICATION - HISTORICAL PERFORMANCE

Track your performance across the previous 12 specimens using this one-page report.



- 1 This shows the lab's score across the last 6 samples. This score is also shown as a percentage.
- 2 This shows the percentages for the lab's country and globally for the last 6 samples. This is broken down by the lab's method and all methods.

- 3 A chart showing the lab's historical performance score. The expected organism for each sample is displayed along the top of the chart.
- 4 A chart showing the percentages for the lab, their country and globally. Each plot is the percentage score for 6 rolling samples.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Antimicrobial susceptibility testing table details all reported antibiotics for current sample and AST response.

Antimicrobial Susceptibility Testing					
Organism: <i>Pseudomonas aeruginosa</i>					
Antibiotic	Resistant	Intermediate	Sensitive	Your Result (Score)	Target
Amikacin	2	2	107	Sensitive (2/2)	Sensitive (Y)
Amoxicillin	2	0	0		Too Few
Amoxicillin/Clavulanic Acid	2	0	0		Too Few
Ampicillin	6	0	1		Resistant (A)
Ampicillin/Sulbactam	1	0	1		Too Few
Azithromycin	0	1	0		Too Few
Aztreonam	1	9	15	Intermediate (N/A)	N/A
Cefazolin	3	1	0		Too Few
Cefepime	2	25	68	Intermediate (2/2)	Intermediate (Y)
Cefixime	2	0	0		Too Few
Cefodime	0	2	3		Too Few
Cefoperazone	0	0	1		Too Few
Cefoperazone/Sulbactam	0	0	1		Too Few
Cefotaxime	8	0	0		Resistant (A)
Cefoxitin	1	0	1		Too Few
Cefpodoxime	1	0	1		Too Few
Ceftazidime	1	29	80	Intermediate (1/2)	Sensitive (A)
Ceftazidime/Avibactam	0	0	5		Sensitive (A)
Ceftolozane/Tazobactam	0	1	6		Sensitive (A)
Ceftriaxone	2	0	0		Too Few
Cefuroxime	3	0	0		Too Few
Ciprofloxacin	0	33	85	Intermediate (2/2)	Intermediate (Y)
Clindamycin	0	0	1		Too Few
Colistin	1	6	17		Sensitive (Y)
Cotrimoxazole	1	0	0		Too Few
Doripenem	0	0	6		Sensitive (A)
Doxycycline	1	0	0		Too Few
Ertapenem	2	0	0		Too Few
Erythromycin	0	0	1		Too Few
Fosfomycin	4	0	0		Too Few
Gentamicin	6	5	80	Sensitive (2/2)	Sensitive (Y)
Imipenem	13	27	57	Intermediate (2/2)	Intermediate (Y)
Levofloxacin	3	15	25	Intermediate (N/A)	N/A

- Target based on 80% agreement or at least 30% more than next common response
- Target requires at least 5 responses or else 'Too Few' is recorded
- Target is based initially on lab's guideline (Y) followed by all guidelines (A) if lab's guideline does not fulfil criteria. If neither of these are met then target recorded as N/A
- Participant responses are recorded for each antibiotic
- Participant responses from an incorrectly or partially identified organism are not included in totals

Scoring

- **If target is Sensitive**
Response of sensitive = 2
Response of intermediate = 1
Response of resistant = 0
- **If target is Resistant**
Response of sensitive = -1
Response of intermediate = 1
Response of resistant = 2

- **If target is Intermediate**
Response of sensitive = 1
Response of intermediate = 2
Response of resistant = 1
- **No scoring possible if target is N/A or Too Few**

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Antimicrobial susceptibility testing table details all reported antibiotics for current sample and AST response.

Ticarcillin/Clavulanic Acid	0	7	1	Intermediate (2/2)	Intermediate (A)
Tigecyclin	11	0	0		Resistant (A)
Tobramycin	1	0	53	Sensitive (2/2)	Sensitive (Y)
Trimethoprim/Sulfamethoxazole	6	2	1		N/A
Vancomycin	0	0	1		Too Few
1 Your Score	19 out of 20		95.0%		
Your Guideline: EUCAST	350 out of 456		76.8%		
All Guidelines	1755 out of 2048		85.7%		
3 of your antibiotics have no target and are not scored					

1 Scoring Summary

- A total score for the participants responses that had targets is provided for the participant

Your Score

- A total score for all antibiotics that had targets is provided for

Your Guideline
All Guidelines

Cefepime				
2 Guideline	Resistant	Intermediate	Sensitive	% Agreement
CLSI	0	0	31	100.0%
EUCAST	1	16	7	66.7%
Unspecified	1	9	30	75.0%

2 Guideline Analysis

- For each antibiotic that has a target assigned, a breakdown of the responses per guideline is provided

MONITORING EQA PERFORMANCE

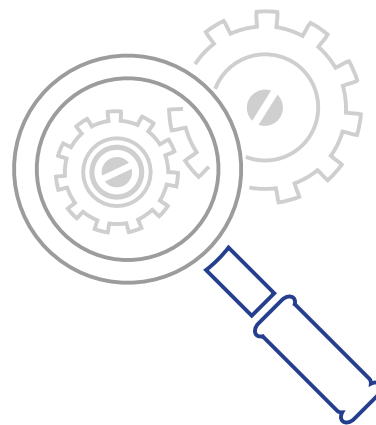
Each EQA report should be evaluated and any poor performance investigated. A step by step approach should be adopted consisting of the following three steps:

1. Investigate the source of the problem

In order to identify the source of the problem, it is useful to be aware of the most common causes of poor EQA performance. Errors can occur at any stage of the testing process; however, EQA is most concerned with detecting analytical errors i.e. errors that occur during the analysis of the sample.

Most analytical errors can be easily divided into three main areas; clerical errors, systematic errors and random errors. Systematic errors result in inaccurate results that consistently show a positive or negative bias. Random errors, on the other hand, affect precision and result in fluctuations in either direction.

It may be possible that, after extensive investigations, the root cause of the poor performance cannot be established. Poor performance for a single sample could be attributed to random error. If poor performance has been noted for several samples, a systematic error is the most likely cause and the analytical process should be reviewed.



Clerical errors

- Transcription errors
- Incorrect units used
- Incorrect sample tested
- Incorrect method classification
- Calculation/conversion error

Systematic errors

- Sample/Reagent prep/handling
- Reagent/calibrator/standardisation change
- Instrument/reagent/calibrator fault
- Inexperienced operators
- Reagent deterioration
- Inappropriate method

Random errors

- Bubbles in reagent
- Bubbles in reagent/sample pipette
- Temperature fluctuations
- Poor pipetting technique
- Poor operator technique

The flowchart (page 29) is designed to help you investigate any apparent poor performance.

2. Implement corrective actions

Some errors can be readily recognised as simple clerical errors and easily corrected. If there is evidence of systematic or random error however more detailed corrective actions must be taken.

Systematic Error

In the event of a systematic error, the following suggested actions may help to resolve the problem:

- Perform instrument maintenance
- Review reagent/sample storage
- Prepare fresh reagents & re-run sample
- Recalibrate instrument
- Check pipettes
- Perform staff training

Random Error

If all possible causes have been excluded, a single unacceptable result is most likely due to random error. Re-run the sample; if the result of repeat analysis is acceptable then corrective action is not required. If the issue persists, investigate possible sources of systematic error.

3. Check the effectiveness of corrective actions

The effectiveness or impact of any corrective actions taken can be assessed by continuing to monitor analytical performance over time.

MONITORING EQA PERFORMANCE

A checklist similar to the one below is extremely useful when investigating poor EQA performance and may help you to determine the root cause of the problem and initiate corrective actions.

Laboratory:
Cycle Number: Sample Number:
Analysis Date: Analyte:
Mean for Comparison: Lab Result: SDI: %Dev:

1. Specimen Handling

- a. Samples received in good condition ☒ Y ☐ N
b. Samples stored/prepared appropriately ☒ Y ☐ N
c. Integrity of the sample is acceptable ☒ Y ☐ N

2. Clerical

- a. Correct result entered ☒ Y ☐ N
b. Correct use of decimal point and units ☒ Y ☐ N
c. Calculations, if any, performed correctly (even if automated) ☒ Y ☐ N
d. Conversion factors applied to results before submission ☒ Y ☐ N

3. Registration and Mean for Comparison

- a. Registered in the correct method/instrument group ☒ Y ☐ N
b. Changed method or instrument without advising RIQAS ☒ Y ☐ N
c. Peer Group changed due to the number of participants returning results e.g. from method to instrument ☒ Y ☐ N
d. An obvious bias between method and instrument means (check histogram and stats sections) ☒ Y ☐ N

4. Internal Quality Control

- a. %Deviation of IQC (at similar conc to that of EQA) on sample analysis date acceptable ☒ Y ☐ N
b. Shift in IQC in the periods just before and after EQA sample analysis ☒ Y ☐ N
c. Trends in IQC in the periods before and after EQA sample analysis ☒ Y ☐ N
d. Random IQC variation on sample analysis date ☒ Y ☐ N

Conclusion:
.....
.....
.....

Lab Manager: Date:

- e. Error due to imprecision; check IQC in terms of %Deviation compared to deviation observed in EQA ☒ Y ☐ N
f. IQC target correctly assigned ☒ Y ☐ N

5. Calibration

- a. Date of last calibration
b. Calibration frequency acceptable ☒ Y ☐ N
c. Last calibration acceptable ☒ Y ☐ N

6. Instrument

- a. Daily maintenance performed on date of sample analysis ☒ Y ☐ N
b. Special maintenance performed prior to sample analysis ☒ Y ☐ N
c. Instrument operated correctly ☒ Y ☐ N
d. Operator fully trained ☒ Y ☐ N

7. Reagents

- a. Reagents prepared and stored correctly ☒ Y ☐ N
b. Reagents within open vial stability ☒ Y ☐ N

8. EQA sample

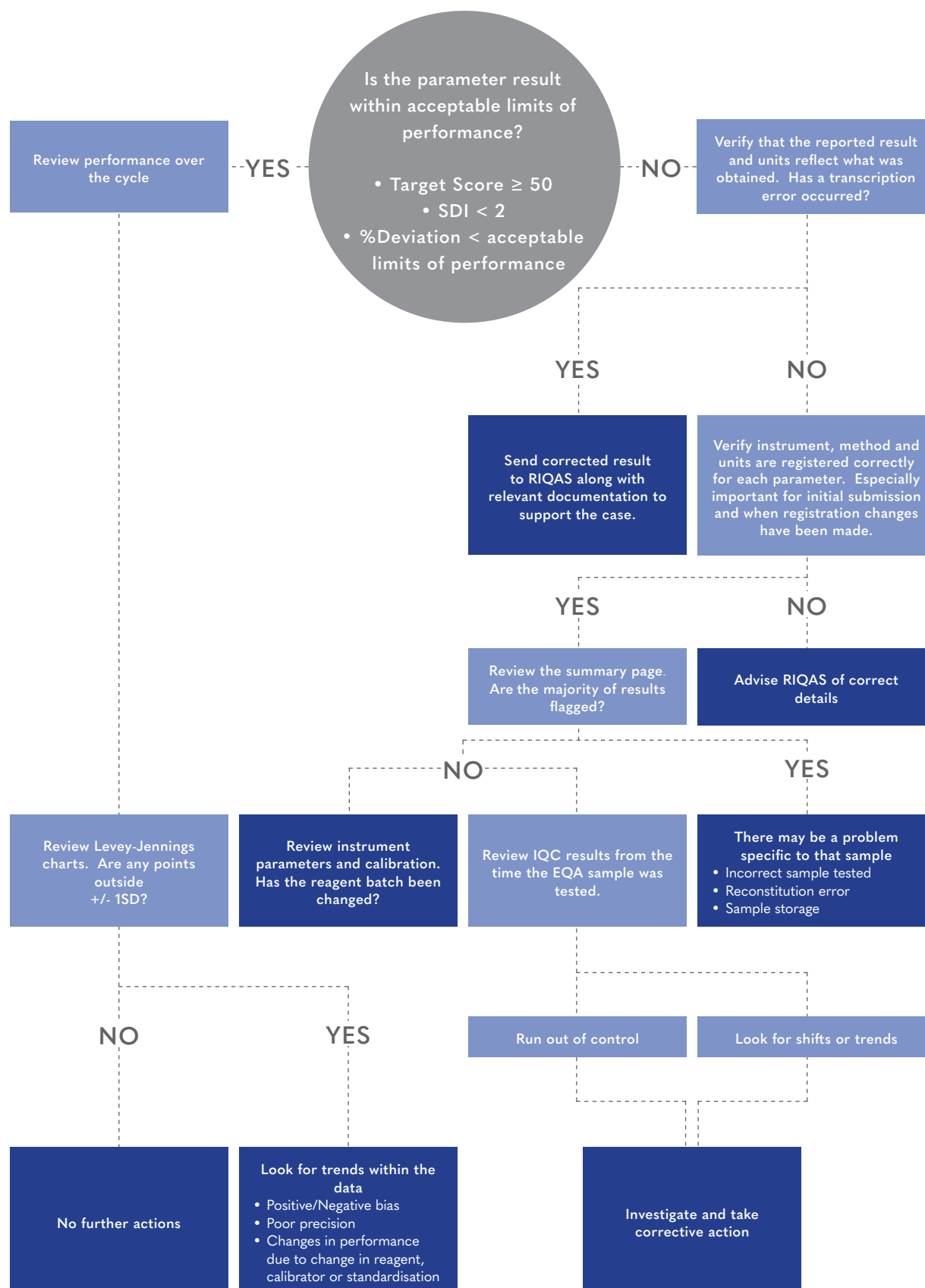
- a. Initial value
b. Re-run value
c. Issue observed in previous EQA samples at a similar concentration (check %Deviation by concentration and Levey Jennings charts) ☒ Y ☐ N
d. All parameters affected (to the same extent) - possible reconstitution error (check %Deviation on summary pages) ☒ Y ☐ N

Remedial Action:
.....
.....
.....

Lab Director: Date:

MONITORING EQA PERFORMANCE

The flow chart below can be used to help identify a possible root cause for poor EQA performance.



RIQAS PROGRAMMES

Ammonia/Ethanol Programme *With target scoring*

RQ9164 (2 ml)
2 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

Ammonia Ethanol

Anti-Müllerian Hormone (AMH) Programme+

RQ9198 (1 ml)
1 Parameter
Samples every month, 1 x 12 month cycle, 12 month subscription

Anti-Müllerian Hormone (AMH)

Anti-TSH Receptor Programme+ *With target scoring*

RQ9174 (1 ml)
1 Parameter
Samples every month, 1 x 12 month cycle, 12 month subscription

Anti-TSH Receptor (TRAb)

Blood Gas Programme *With target scoring*

RQ9134 (1.8 ml) First registered instrument 11 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription	RQ9134/A (1.8 ml) Subsequent instruments 11 Parameters
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Bicarbonate Ca++ Cl-	CO ₂ (Total) Glucose Lactate	K+ Na+ pCO ₂	pH pO ₂
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BNP Programme+ *With target scoring*

RQ9165 (1 ml)
1 Parameter
Samples every month, 1 x 12 month cycle, 12 month subscription

BNP

Cardiac Programme *With target scoring*

RQ9127/a (1 ml) 2 Parameters only (choose from 7) Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription	RQ9127/b (1 ml) Full 7 Parameters 12 month subscription	RQ9186 (1 ml) Full 7 Parameters Samples every month, 1 x 12 monthly cycle, 12 month subscription
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CK, Total CK-MB (Activity)	CK-MB (Mass) Homocysteine	Myoglobin Troponin I	Troponin T
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Cardiac Plus Programme *With target scoring*

RQ9190 (3 ml)
11 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

CK, Total CK-MB Activity CK-MB Mass	D-dimer Digoxin Homocysteine	hsCRP Myoglobin NT proBNP	Troponin I Troponin T
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Cerebrospinal Fluid Programme+ *With target scoring*

RQ9168 (3 ml)
7 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

Albumin Chloride	Glucose IgG	Lactate Protein (Total)	Sodium
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= Liquid ready-to-use samples



= Lyophilised samples

PURPLE = The only parameters available on RQ9135/a

+ = Not accredited

* = Pilot study ongoing

RIQAS PROGRAMMES

Coagulation Programme *With target scoring*

RQ9135/a (1 ml) 5 Selected parameters only + 1 pilot (aPTT, PT, TT, Fibrinogen, Antithrombin III) Samples every month, 1 x 12 month cycle, 12 month subscription		RQ9135/b (1 ml) Full 16 Parameters + 1 pilot	
aPTT PT (including INR) TT Fibrinogen Antithrombin III	D-dimer* Factor II Factor V Factor VII Factor VIII	Factor IX Factor X Factor XI Factor XII Plasminogen	Protein C Protein S

CO-Oximetry Programme+

RQ9177 (1.2 ml) First registered instrument 7 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription		RQ9177/A (1.2 ml) Subsequent instruments 7 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription	
Carboxyhaemoglobin (COHb / HbCO) Deoxyhaemoglobin (HHb)	Methaemoglobin (MetHb) Oxygen Content (O2CT)	Oxygen Saturation (sO2 / Vol O2) Oxyhaemoglobin (O2Hb / HbO2)	Total Haemoglobin (tHb)

CYFRA 21-1 Programme+

RQ9175 (1 ml) 1 Parameter Samples every month, 1 x 12 month cycle, 12 month subscription			
CYFRA 21-1 (Cytokeratin 19)			

Cytokines Programme+

RQ9195 (1 ml) 1 Parameter + 11 pilots Samples every month, 1 x 12 month cycle, 12 month subscription			
Epidermal Growth Factor (EGF)* Interleukin – 1 alpha (IL-1α)* Interleukin – 1 beta (IL-1β)* Interleukin – 2 (IL-2)*	Interleukin – 4 (IL-4)* Interleukin – 6 (IL-6) Interleukin – 8 (IL-8)* Interleukin – 10 (IL-10)*	Interferon gamma (INF-γ)* Monocyte Chemoattractant Protein -1 (MCP-1)* Tumour Necrosis Factor alpha (TNF-α)*	Vascular Endothelial Growth Factor (VEGF)*

ESR Programme+

RQ9163 (4.5 ml) 1 Parameter 2 samples per quarterly distribution, 1 x 12 month cycle, 12 month subscription	
ESR (Erythrocyte Sedimentation Rate)	

General Clinical Chemistry Programme *With target scoring*

RQ9112/a (5 ml) 10 Parameters Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, reference method values	RQ9112/b (5 ml) 17 Parameters	RQ9112/c (5 ml) Full 56 Parameters	RQ9128 (5ml) Full 56 Parameters Samples every month, 1 x 12 monthly cycle, 12 month subscription
ACE (Angiotensin Converting Enzyme) Acid Phosphatase (Prostatic) Acid Phosphatase (Total) Albumin Alkaline Phosphatase ALT (ALAT) Amylase (Pancreatic) Amylase (Total) AST (ASAT) Bicarbonate Bile Acids Bilirubin (Direct) Bilirubin (Total) Calcium	Calcium, Adjusted Calcium (Ionised) Chloride Cholesterol Cholinesterase CK, Total (CPK) Copper Creatinine D-3-Hydroxybutyrate eGFR (estimated glomerular filtration rate) Fructosamine γGT GLDH Glucose	HBDH HDL-Cholesterol Iron Lactate LD (LDH) LDL-Cholesterol Lipase Lithium Magnesium NEFA Non-HDL Cholesterol Osmolality Phosphate (Inorganic) Potassium	Protein (Total) PSA Sodium TIBC T ₃ (Free) T ₃ (Total) T ₄ (Free) T ₄ (Total) Triglycerides TSH UIBC Urea Uric Acid Zinc

Glycated Haemoglobin Programme (HbA1c) *With target scoring*

RQ9129 (0.5ml) 2 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription	
HbA1c	Total Haemoglobin

 = Liquid ready-to-use samples

 = Lyophilised samples

PURPLE = The only parameters available on RQ9135/a

+ = Not accredited

* = Pilot study ongoing

RIQAS PROGRAMMES

Haematology Programme *With target scoring*



RQ9118 (2 ml) 11 Parameters Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription	RQ9140 (2ml) 11 Parameters Samples every month, 1 x 12 monthly cycle, 12 month subscription
Haematocrit (HCT) Haemoglobin (Hb) Mean Cell Haemoglobin (MCH)	Mean Cell Haemoglobin Concentration (MCHC) Mean Cell Volume (MCV) Mean Platelet Volume (MPV) Platelets (PLT) Plateletcrit (PCT) Red Blood Cell Count (RBC) Red Cell Distribution Width (RDW) Total White Blood Cell Count (WBC)

Human Urine Programme *With target scoring*



RQ9115 (2 x 10 ml) 25 Parameters Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription	RQ9185 (10ml) 25 Parameters Samples every month, 1 x 12 monthly cycle, 12 month subscription
--	---

ACR Albumin/Microalbumin Amylase Calcium Chloride Copper Cortisol	Creatinine Dopamine Epinephrine Glucose Metanephrine Norepinephrine	Normetanephrine Magnesium Osmolality Oxalate Phosphate (Inorganic) Potassium	Protein (Total) Sodium Urea Uric Acid VMA 5-HIAA
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Immunoassay Programme *With target scoring*



RQ9125/a (5 ml) 4 Parameters only + 2 pilots Samples every two weeks, 2 x 6 monthly cycles, 12 month subscription (RQ9125/a, RQ9125/b, RQ9125/c)	RQ9125/b (5 ml) 13 Parameters only + 2 pilots	RQ9125/c (5 ml) Full 49 Parameters + 2 pilots	RQ9130 (5 ml) Full 49 Parameters + 2 pilots Samples every month, 1 x 12 month cycle, 12 month subscription RQ9130)
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ACTH AFP Aldosterone Amikacin Androstenedione β-2-Microglobulin CA125 CA15-3 CA19-9 Carbamazepine CEA Cortisol C-Peptide	DHEA-Sulphate DHEA Unconjugated Digoxin Ferritin Folate FSH Gentamicin GH hCG IgE Insulin LH Oestradiol	17-OH-Progesterone Paracetamol Phenobarbital Phenytoin Progesterone Prolactin PSA (Free) PSA (Total) PTH Salicylate SHBG T ₃ (Free) T ₃ (Total)	T ₄ (Free) T ₄ (Total) Testosterone (Free)* Testosterone (Total) Theophylline Thyroglobulin TSH Valproic Acid Vancomycin Vitamin B12 1-25-(OH) ₂ -Vitamin D* 25-OH-Vitamin D
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Immunoassay Speciality 1 Programme *With target scoring*



RQ9141 (2 ml) 9 Parameters + 1 pilot Samples every month, 1 x 12 month cycle, 12 month subscription	1-25-(OH) ₂ -Vitamin D* 25-OH-Vitamin D C-Peptide	Anti-TG Anti-TPO IGF-1	Osteocalcin Procalcitonin PTH	Insulin
--	--	------------------------------	-------------------------------------	---------

Immunoassay Speciality 2 Programme *With target scoring*



RQ9142 (1 ml) 5 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription	Calcitonin Gastrin	Procalcitonin	Plasma Renin Activity	Renin (Direct Concentration)
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Immunosuppressant Programme+



RQ9159 (2 ml) 4 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription, reference method values	Ciclosporin	Everolimus	Sirolimus	Tacrolimus
---	-------------	------------	-----------	------------

Lipid Programme *With target scoring*



RQ9126/a (3 ml) 3 Parameters only (choose from 7) Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription	RQ9126/b (3 ml) Full 7 Parameters	Apolipoprotein A1 Apolipoprotein B	Cholesterol (Total) HDL-Cholesterol	LDL-Cholesterol Lipoprotein (a)	Triglycerides
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= Liquid ready-to-use samples



= Lyophilised samples

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RIQAS PROGRAMMES

Maternal Screening Programme *With target scoring*

RQ9137 (1 ml)
6 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

AFP
free β -hCG

Total hCG
Inhibin A

PAPP-A

Unconjugated Oestriol

Microbiology (Bacterial Identification) Programme+

RQ9197
1 strain (complete with case study)
Samples every 2 months, 1 x 12 month cycles, 12 month subscription

1 strain complete with case study. Identification of the micro-organisms can be made at Gram positive / negative, Genus and Species level. Antimicrobial Susceptibility Testing on identified strain

Antimicrobial Susceptibility Testing

Strain Identification

Neonatal Bilirubin Programme+

RQ9191 (3 ml)
2 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

Direct Bilirubin

Total Bilirubin

Psychiatric Drugs Programme

Serology (Anti-SARS-CoV-2) Programme+

RQ9193 (0.5 ml)
3 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

IgG

IgM

Total Antibodies

Serology (EBV) Programme+

RQ9153 (1 ml)
3 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-EBV VCA IgG

Anti-EBNA IgG

Anti-EBV VCA IgM

Serology (HIV-Hepatitis) Programme+

RQ9151 (1.8 ml)
10 Parameters + 6 pilots
Samples every month, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-CMV (Total)
Anti-HAV IgM*
Anti-HAV (Total)*
Anti-HBc

Anti-HBc IgM*
Anti-HBe (Total)*
Anti-HBs (Total)*
Anti-HCV

Anti-HIV1
Anti-HIV2
Anti-HIV combined
Anti-HTLV I

Anti-HTLV II
Anti-HTLV combined
HBsAg
P24*

Serology (Syphilis) Programme+

RQ9154 (1 ml)
1 Parameter
Samples every month, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Syphilis (Methods available include immunoassay RPR, VDRL and TPHA)

Serology (ToRCH) Programme+

RQ9152 (1 ml)
12 Parameters + 3 pilots
Samples every month, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-CMV IgG
Anti-CMV IgM
Anti-HSV1 IgG
Anti-HSV1 IgM

Anti-HSV2 IgG
Anti-HSV2 IgM
Anti-HSV1/2 IgG
Anti-HSV1/2 IgM

Anti-Measles IgG*
Anti-Mumps IgG*
Anti-Rubella IgG
Anti-Rubella IgM

Anti-Toxoplasma IgG
Anti-Toxoplasma IgM
Anti-VZV IgG*



= Liquid ready-to-use samples



= Lyophilised samples

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PARAMETER INDEX

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		Ammonia / Ethanol	Anti-Mullerian Hormone (AMH) +	Anti-TSH Receptor +	Blood Gas	BNP +	Cardiac	Cardiac Plus	Cerebrospinal Fluid +	Coagulation	CO-Oximetry +	CYFRA 21-1 +	Cytokines +	ESR +	General Clinical Chemistry	HbA1c	Haematology	Human Urine	Immunoassay
#	1-25-(OH) ₂ -Vitamin D*																		X
	17-OH-Progesterone																		X
	25-OH-Vitamin D																		X
	5-HIAA																	X	
A	α-1-Acid Glycoprotein																		
	α-1-Antitrypsin																		
	α-2-Macroglobulin																		
	ACE (Angiotensin Converting Enzyme)														X				
	Acid Phosphatase (Prostatic)														X				
	Acid Phosphatase (Total)														X				
	ACR																	X	
	ACTH																		X
	AFP																		X
	Albumin								X						X			X	
	Aldosterone																		X
	Alkaline Phosphatase														X				
	ALT																		
	ALT (ALAT)														X				
	Amikacin																		X
	Ammonia	X																	
	Amylase (Pancreatic)														X				
	Amylase (Total)														X			X	
	Androstenedione																		X
	Anti Streptolysin O (ASO)																		
	Anti-CMV																		
	Anti-CMV IgG																		
	Anti-CMV IgM																		
	Anti-EBNA IgG																		
	Anti-EBV VCA IgG																		
	Anti-EBV VCA IgM																		
	Anti-HAV IgM*																		
	Anti-HAV (Total)*																		
	Anti-HBc																		
	Anti-HBc IgM*																		
	Anti-HBe (Total)*																		
	Anti-HBs (Total)*																		
	Anti-HCV																		
	Anti-HIV-1																		
	Anti-HIV-1 & 2 Combined																		
	Anti-HIV-2																		
	Anti-HSV-1 & 2 IgG Combined																		
	Anti-HSV-1 & 2 IgM Combined																		
	Anti-HSV1 IgG																		
	Anti-HSV1 IgM																		
	Anti-HSV2 IgG																		
	Anti-HSV2 IgM																		
	Anti-HTLV-1 & 2 Combined																		
	Anti-HTLV-I																		
	Anti-HTLV-II																		
	Anti-Measles IgG*																		
	Antimicrobial Susceptibility Testing																		

^Δ Pilot status only in certain programmes. Please check pages 42-46 for more information.

PARAMETER INDEX

Immunoassay Speciality 1	Immunoassay Speciality 2	Immunosuppressant +	Lipid	Maternal Screening	Microbiology (Bacterial Identification) +	Neonatal Bilirubin +	Serology (Anti-SARS-CoV-2) +	Serology (EBV) +	Serology (HIV / Hepatitis) +	Serology (Syphilis) +	Serology (ToRCH) +	Serum Indices +	Specific Proteins	Sweat Testing +	Therapeutic Drug	Urinalysis	Urine Toxicology +		
X																		1-25-(OH) ₂ -Vitamin D*	#
																		17-OH-Progesterone	
X																		25-OH-Vitamin D	
																		5-HIAA	
													X					α-1-Acid Glycoprotein	A
													X					α-1-Antitrypsin	
													X					α-2-Macroglobulin	
																		ACE (Angiotensin Converting Enzyme)	
																		Acid Phosphatase (Prostatic)	
																		Acid Phosphatase (Total)	
																		ACR	
																		ACTH	
				X									X					AFP	
													X			X		Albumin	
																		Aldosterone	
												X						Alkaline Phosphatase	
												X						ALT	
																		ALT (ALAT)	
															X			Amikacin	
																		Ammonia	
																		Amylase (Pancreatic)	
																		Amylase (Total)	
																		Androstenedione	
													X					Anti Streptolysin O (ASO)	
									X									Anti-CMV	
											X							Anti-CMV IgG	
											X							Anti-CMV IgM	
								X										Anti-EBNA IgG	
								X										Anti-EBV VCA IgG	
								X										Anti-EBV VCA IgM	
									X									Anti-HAV IgM*	
									X									Anti-HAV (Total)*	
									X									Anti-HBc	
									X									Anti-HBc IgM*	
									X									Anti-HBe (Total)*	
									X									Anti-HBs (Total)*	
									X									Anti-HCV	
									X									Anti-HIV-1	
									X									Anti-HIV-1 & 2 Combined	
									X									Anti-HIV-2	
											X							Anti-HSV-1 & 2 IgG Combined	
											X							Anti-HSV-1 & 2 IgM Combined	
											X							Anti-HSV1 IgG	
											X							Anti-HSV1 IgM	
											X							Anti-HSV2 IgG	
											X							Anti-HSV2 IgM	
									X									Anti-HTLV-1 & 2 Combined	
									X									Anti-HTLV-I	
									X									Anti-HTLV-II	
											X							Anti-Measles IgG*	
					X													Antimicrobial Susceptibility Testing	

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		Ammonia / Ethanol	Anti-Müllerian Hormone (AMH) +	Anti-TSH Receptor +	Blood Gas	BNP +	Cardiac	Cardiac Plus	Cerebrospinal Fluid +	Coagulation	CO-Oximetry +	CYFRA 21-1 +	Cytokines +	ESR +	General Clinical Chemistry	HbA1c	Haematology	Human Urine	Immunoassay
A	Anti-Müllerian Hormone (AMH)		X																
	Anti-Mumps IgG*																		
	Anti-Rubella IgG																		
	Anti-Rubella IgM																		
	Anti-SARS-COV2 IgG																		
	Anti-SARS-COV2 IgM																		
	Anti-SARS-COV2 Total																		
	Anti-TG																		
	Antithrombin III									X									
	Anti-Toxoplasma IgG																		
	Anti-Toxoplasma IgM																		
	Anti-TPO																		
	Anti-TSH Receptor (TRAb)			X															
	Anti-VZV IgG*																		
	Apolipoprotein AI																		
	Apolipoprotein B																		
	aPTT									X									
	AST																		
	AST (ASAT)														X				
B	β-2-Microglobulin																		X
	Benzoylcegonine																		
	Bicarbonate				X										X				
	Bile Acids														X				
	Bilirubin (Direct)														X				
	Bilirubin (Total)														X				
	Blood																		
	BNP					X													
	Buprenorphine																		
C	CA15-3																		X
	CA19-9																		X
	CA125																		X
	Caffeine																		
	Calcitonin																		
	Calcium														X		X		
	Calcium, Adjusted														X				
	Calcium (Ionised)				X										X				
	Cannabinoids (THC)																		
	Carbamazepine																		X
	Carboxyhaemoglobin (COHb / HbCO)										X								
	CEA																		X
	Ceruloplasmin																		
	Chloride				X				X						X		X		
	Cholesterol (Total)														X				
	Cholinesterase														X				
	Ciclosporin																		
	CK, Total						X	X							X				
	CK-MB (Activity)						X	X											
	CK-MB (Mass)						X	X											
	CK NAC																		
	CO2, Total				X														
	Complement C ₃																		

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PARAMETER INDEX

Immunoassay Speciality 1	Immunoassay Speciality 2	Immunosuppressant +	Lipid	Maternal Screening	Microbiology (Bacterial Identification) +	Neonatal Bilirubin +	Serology (Anti-SARS-CoV-2) +	Serology (EBV) +	Serology (HIV / Hepatitis) +	Serology (Syphilis) +	Serology (ToRCH) +	Serum Indices +	Specific Proteins	Sweat Testing +	Therapeutic Drug	Urinalysis	Urine Toxicology +			
											X							Anti-Müllerian Hormone (AMH)	A	
											X							Anti-Mumps IgG*		
											X							Anti-Rubella IgG		
											X							Anti-Rubella IgM		
						X												Anti-SARS-COV2 IgG		
						X												Anti-SARS-COV2 IgM		
						X												Anti-SARS-COV2 Total		
X																		Anti-TG		
													X					Antithrombin III		
											X							Anti-Toxoplasma IgG		
											X							Anti-Toxoplasma IgM		
X																		Anti-TPO		
																		Anti-TSH Receptor (TRAb)		
											X							Anti-VZV IgG*		
			X															Apolipoprotein AI		
			X															Apolipoprotein B		
																		aPTT		
												X						AST		
																		AST (ASAT)		
													X					β-2-Microglobulin	B	
																	X	Benzoylcegonine		
																		Bicarbonate		
						X						X						Bile Acids		
						X						X					X	Bilirubin (Direct)		
																	X	Bilirubin (Total)		
																	X	Blood		
																		BNP		
																	X	Buprenorphine		
																				C
																		CA15-3		
																		CA19-9		
																		CA125		
	X														X			Caffeine		
																		Calcitonin		
												X						Calcium		
																		Calcium, Adjusted		
																		Calcium (Ionised)		
																	X	Cannabinoids (THC)		
															X			Carbamazepine		
																		Carboxyhaemoglobin (COHb / HbCO)		
																		CEA		
													X					Ceruloplasmin		
			X									X		X				Chloride		
												X						Cholesterol (Total)		
																		Cholinesterase		
		X													X			Ciclosporin		
																		CK, Total		
																		CK-MB (Activity)		
																		CK-MB (Mass)		
												X						CK NAC		
																		CO2, Total		
													X					Complement C ₃		

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		Ammonia / Ethanol	Anti-Mullerian Hormone (AMH) +	Anti-TSH Receptor +	Blood Gas	BNP +	Cardiac	Cardiac Plus	Cerebrospinal Fluid +	Coagulation	CO-Oximetry +	CYFRA 21-1 +	Cytokines +	ESR +	General Clinical Chemistry	HbA1c	Haematology	Human Urine	Immunoassay
C	Complement C ₄																		
	Conductivity																		
	Copper														X			X	
	Cortisol																	X	X
	Cotinine																		
	C-Peptide																		X
	C-Reactive Protein (CRP)																		
	Creatinine														X			X	
	CYFRA 21-1 (Cytokeratin 19)											X							
D	D-3-Hydroxybutyrate														X				
	d-Amphetamine																		
	D-Dimer* ^Δ							X		X									
	Deoxyhaemoglobin (HHb)										X								
	DHEA Unconjugated																		X
	DHEA-Sulphate																		X
	Digoxin							X											X
	d-Methamphetamine																		
	Dopamine																	X	
E	EDDP																		
	eGFR (estimated glomerular filtration rate)														X				
	Epidermal Growth Factor (EGF)*												X						
	Epinephrine																	X	
	ESR													X					
	Ethanol	X																	
	Ethosuximide																		
	Everolimus																		
F	Factor II									X									
	Factor IX									X									
	Factor V									X									
	Factor VII									X									
	Factor VIII									X									
	Factor X									X									
	Factor XI									X									
	Factor XII									X									
	Ferritin																		X
	Fibrinogen									X									
	Folate																		X
	Free Morphine																		
	free β-hCG																		
	Fructosamine														X				
	FSH																		X
G	γ-GT														X				
	Galactose																		
	Gastrin																		
	Gentamicin																		X
	Growth Hormone (GH)																		X
	GLDH														X				
	Glucose				X				X						X			X	
H	Haematocrit (HCT)																	X	
	Haemoglobin (Hb)																	X	
	Total Haemoglobin (tHb)										X					X			

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PARAMETER INDEX

Immunoassay Speciality 1	Immunoassay Speciality 2	Immunosuppressant +	Lipid	Maternal Screening	Microbiology (Bacterial Identification) +	Neonatal Bilirubin +	Serology (Anti-SARS-CoV-2) +	Serology (EBV) +	Serology (HIV / Hepatitis) +	Serology (Syphilis) +	Serology (ToRCH) +	Serum Indices +	Specific Proteins	Sweat Testing +	Therapeutic Drug	Urinalysis	Urine Toxicology +
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													X				Complement C ₄	C
														X			Conductivity	
																	Copper	
																	Cortisol	
X																X	Cotinine	
													X				C-Peptide	
												X					C-Reactive Protein (CRP)	
											X				X	X	Creatinine	
																	CYFRA 21-1 (Cytokeratin 19)	D
																	D-3-Hydroxybutyrate	
																X	d-Amphetamine	
																	D-Dimer* ^Δ	
																	Deoxyhaemoglobin (HHb)	
																	DHEA Unconjugated	
															X		DHEA-Sulphate	
																X	Digoxin	
																	d-Methamphetamine	E
																	Dopamine	
																X	EDDP	
																	eGFR (estimated glomerular filtration rate)	
																	Epidermal Growth Factor (EGF)*	
																	Epinephrine	
																	ESR	
																X	Ethanol	
		X													X		Ethosuximide	F
																	Everolimus	
																	Factor II	
																	Factor IX	
																	Factor V	
																	Factor VII	
																	Factor VIII	
																	Factor X	
																	Factor XI	
																	Factor XII	
													X				Ferritin	
																	Fibrinogen	
																	Folate	
																X	Free Morphine	
																	free β-hCG	
																	Fructosamine	
																	FSH	G
												X					γ-GT	
	X															X	Galactose	
																	Gastrin	
															X		Gentamicin	
																	Growth Hormone (GH)	
																	GLDH	
												X				X	Glucose	
																	Haematocrit (HCT)	H
																	Haemoglobin (Hb)	
																	Total Haemoglobin (tHb)	

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		Ammonia / Ethanol	Anti-Mullerian Hormone (AMH) +	Anti-TSH Receptor +	Blood Gas	BNP +	Cardiac	Cardiac Plus	Cerebrospinal Fluid +	Coagulation	CO-Oximetry +	CYFRA 21-1 +	Cytokines +	ESR +	General Clinical Chemistry	HbA1c	Haematology	Human Urine	Immunoassay
H	Haemolysis																		
	Haptoglobin																		
	HbA1c															X			
	HBsAg																		
	HBDH													X					
	hCG																	X	
	HDL-Cholesterol													X					
	Homocysteine						X	X											
	hsCRP							X											
I	Icteric																		
	IgA																		
	IgE																	X	
	IGF-1																		
	IgG								X										
	IgM																		
	Inhibin A																		
	Insulin																	X	
	Interferon gamma (INF-γ)*												X						
	Interleukin - 1 alpha (IL-1α)*												X						
	Interleukin - 1 beta (IL-1β)*												X						
	Interleukin - 10 (IL-10)*												X						
	Interleukin - 2 (IL-2)*												X						
	Interleukin - 4 (IL-4)*												X						
	Interleukin - 6 (IL-6)												X						
	Interleukin - 8 (IL-8)*												X						
	Iron													X					
K	Kappa Light Chain (Free)																		
	Kappa Light Chain (Total)																		
	Ketones																		
L	Lactate				X				X						X				
	Lambda Light Chain (Free)																		
	Lambda Light Chain (Total)																		
	LD (LDH)														X				
	LDL-Cholesterol														X				
	Leucocytes																		
	Lipase														X				
	Lipoprotein (a)																		
	Lithium														X				
	Lorazepam																		
	LSD																		
	Luteinising Hormone (LH)																	X	
M	Magnesium														X			X	
	MDMA																		
	Mean Cell Haemoglobin (MCH)																X		
	Mean Cell Haemoglobin Concentration (MCHC)																X		
	Mean Cell Volume (MCV)																X		
	Mean Platelet Volume (MPV)																X		
	Metanephrine																	X	
	Methadone																		
	Methaemoglobin (MetHb)										X								
	Methotrexate																		

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PARAMETER INDEX

Immunoassay Speciality 1	Immunoassay Speciality 2	Immunosuppressant +	Lipid	Maternal Screening	Microbiology (Bacterial Identification) +	Neonatal Bilirubin +	Serology (Anti-SARS-CoV-2) +	Serology (EBV) +	Serology (HIV / Hepatitis) +	Serology (Syphilis) +	Serology (ToRCH) +	Serum Indices +	Specific Proteins	Sweat Testing +	Therapeutic Drug	Urinalysis	Urine Toxicology +		
												X						Haemolysis	H
													X					Haptoglobin	
																		HbA1c	
								X										HBsAg	
																		HBDH	
																X		hCG	
			X									X						HDL-Cholesterol	
																		Homocysteine	
																		hsCRP	
												X						Icteric	I
													X					IgA	
													X					IgE	
X																		IGF-1	
													X					IgG	
													X					IgM	
				X														Inhibin A	
X																		Insulin	
																		Interferon gamma (INF-γ)*	
																		Interleukin – 1 alpha (IL-1α)*	
																		Interleukin – 1 beta (IL-1β)*	
																		Interleukin – 10 (IL-10)*	
																		Interleukin – 2 (IL-2)*	
																		Interleukin – 4 (IL-4)*	
																		Interleukin – 6 (IL-6)	
																		Interleukin – 8 (IL-8)*	
												X						Iron	
													X					Kappa Light Chain (Free)	K
													X					Kappa Light Chain (Total)	
																X		Ketones	
												X						Lactate	L
													X					Lambda Light Chain (Free)	
													X					Lambda Light Chain (Total)	
												X						LD (LDH)	
			X															LDL-Cholesterol	
																X		Leucocytes	
												X						Lipase	
			X															Lipoprotein (a)	
															X			Lithium	
																	X	Lorazepam	
																	X	LSD	
																		Luteinising Hormone (LH)	
												X						Magnesium	M
																	X	MDMA	
																		Mean Cell Haemoglobin (MCH)	
																		Mean Cell Haemoglobin Concentration (MCHC)	
																		Mean Cell Volume (MCV)	
																		Mean Platelet Volume (MPV)	
																		Metanephrine	
																	X	Methadone	
																		Methaemoglobin (MetHb)	
															X			Methotrexate	

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		Ammonia / Ethanol	Anti-Mullerian Hormone (AMH) +	Anti-TSH Receptor +	Blood Gas	BNP +	Cardiac	Cardiac Plus	Cerebrospinal Fluid +	Coagulation	CO-Oximetry +	CYFRA 21-1 +	Cytokines +	ESR +	General Clinical Chemistry	HbA1c	Haematology	Human Urine	Immunoassay
M	Monocyte Chemoattractant Protein -1 (MCP-1)*												X						
	Myoglobin						X	X											
N	NEFA														X				
	Nitrite														X				
	Non-HDL Cholesterol														X				
	Norepinephrine																	X	
	Normetanephrine																	X	
	Norpropoxyphene																		
	Nortriptyline																		
	NTproBNP							X											
O	Oestradiol																		X
	Osmolality														X			X	
	Osteocalcin																	X	
	Oxalate																	X	
	Oxazepam																		
	Oxygen Content (O2CT)										X								
	Oxygen Saturation (sO2 / Vol O2)										X								
	Oxyhaemoglobin (O2Hb / HbO2)										X								
P	P24*																		
	PAPP-A																		
	Paracetamol (Acetaminophen)																		X
	pCO ₂				X														
	pH				X														
	Phencyclidine																		
	Phenobarbital																		X
	Phenytoin																		X
	Phosphate (Inorganic)														X			X	
	Plasma Renin Activity																		
	Plasminogen									X									
	Plateletcrit (PCT)																X		
	Platelets (PLT)																X		
	pO ₂				X														
	Potassium				X										X			X	
	Prealbumin (Transthyretin)																		
	Primidone																		
	Procalcitonin																		
	Progesterone																		X
	Prolactin																		X
	Protein (Total)								X						X			X	
	Protein C									X									
	Protein S									X									
	PSA (Free)																		X
	PSA (Total)														X				X
	PT (Including INR)									X									
	PTH																		X
R	Red Blood Cell Count (RBC)																X		
	Red Cell Distribution Width (RDW)																X		
	Renin (Direct Concentration)																		
	Retinol Binding Protein																		
	Rheumatoid Factor																		
S	Salicylic Acid																		X

^Δ Pilot status only in certain programmes. Please check pages 42-46 for more information.

PARAMETER INDEX

Immunoassay Speciality 1	Immunoassay Speciality 2	Immunosuppressant +	Lipid	Maternal Screening	Microbiology (Bacterial Identification) +	Neonatal Bilirubin +	Serology (Anti-SARS-CoV-2) +	Serology (EBV) +	Serology (HIV / Hepatitis) +	Serology (Syphilis) +	Serology (ToRCH) +	Serum Indices +	Specific Proteins	Sweat Testing +	Therapeutic Drug	Urinalysis	Urine Toxicology +		
																		Monocyte Chemoattractant Protein -1 (MCP-1)*	M
																		Myoglobin	
																		NEFA	N
																X		Nitrite	
																		Non-HDL Cholesterol	
																		Norepinephrine	
																		Normetanephrine	
																	X	Norpropoxyphene	
																	X	Nortriptyline	
																		NTproBNP	
																		Oestradiol	O
X																		Osmolality	
																		Osteocalcin	
																		Oxalate	
																	X	Oxazepam	
																		Oxygen Content (O2CT)	
																		Oxygen Saturation (sO2 / Vol O2)	
																		Oxyhaemoglobin (O2Hb / HbO2)	
									X									P24*	P
				X														PAPP-A	
															X			Paracetamol (Acetaminophen)	
																		pCO ₂	
																X		pH	
																	X	Phencyclidine	
															X		X	Phenobarbital	
															X			Phenytoin	
												X						Phosphate (Inorganic)	
X																		Plasma Renin Activity	
																		Plasminogen	
																		Plateletcrit (PCT)	
																		Platelets (PLT)	
																		pO ₂	
													X					Potassium	
														X				Prealbumin (Transthyretin)	
															X			Primidone	
X	X																	Procalcitonin	
																		Progesterone	
																		Prolactin	
												X					X	Protein (Total)	
																		Protein C	
																		Protein S	
																		PSA (Free)	
																		PSA (Total)	
																		PT (Including INR)	
X																		PTH	
																		Red Blood Cell Count (RBC)	R
																		Red Cell Distribution Width (RDW)	
	X																	Renin (Direct Concentration)	
													X					Retinol Binding Protein	
													X					Rheumatoid Factor	
															X			Salicylic Acid	S

+ = Not accredited

* = Pilot study ongoing

PURPLE = The only parameters available on RQ9135/a

^a Pilot status only in certain programmes. Please check pages 42-46 for more information.

PARAMETER INDEX

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		Ammonia / Ethanol	Anti-Mullerian Hormone (AMH) +	Anti-TSH Receptor +	Blood Gas	BNP +	Cardiac	Cardiac Plus	Cerebrospinal Fluid +	Coagulation	CO-Oximetry +	CYFRA 21-1 +	Cytokines +	ESR +	General Clinical Chemistry	HbA1c	Haematology	Human Urine	Immunoassay
S	Secobarbital																		
	SHBG																		X
	Sirolimus																		
	Sodium				X				X						X			X	
	Specific Gravity																		
	Strain Identification																		
	Syphilis																		
T	T ₃ (Free)														X				X
	T ₃ (Total)														X				X
	T ₄ (Free)														X				X
	T ₄ (Total)														X				X
	Tacrolimus																		
	Testosterone (Free)*																		X
	Testosterone (Total)																		X
	Theophylline																		X
	Thyroglobulin																		X
	TIBC														X				
	Tobramycin																		
	Total hCG																		
	Transferrin																		
	Triglycerides														X				
	Troponin I						X	X											
	Troponin T						X	X											
	TSH														X				X
	TT									X									
	Tumour Necrosis Factor alpha (TNF-α)*												X						
U	UIBC														X				
	Unconjugated Oestriol																		
	Urea														X			X	
	Uric Acid														X			X	
	Urobilinogen																		
V	Valproic Acid																		X
	Vancomycin																		X
	Vascular Endothelial Growth Factor (VEGF)*												X						
	Vitamin B12																		X
	VMA																	X	
W	Total White Blood Cell Count (WBC)																X		
Z	Zinc														X				

Δ Pilot status only in certain programmes. Please check pages 42-46 for more information.

PARAMETER INDEX

Immunoassay Speciality 1	Immunoassay Speciality 2	Immunosuppressant +	Lipid	Maternal Screening	Microbiology (Bacterial Identification) +	Neonatal Bilirubin +	Serology (Anti-SARS-CoV-2) +	Serology (EBV) +	Serology (HIV / Hepatitis) +	Serology (Syphilis) +	Serology (ToRCH) +	Serum Indices +	Specific Proteins	Sweat Testing +	Therapeutic Drug	Urinalysis	Urine Toxicology +		
																	X	Secobarbital	S
		X																SHBG	
												X						Sirolimus	
																		Sodium	
					X											X		Specific Gravity	
										X								Strain Identification	
																		Syphilis	
																		T ₃ (Free)	T
																		T ₃ (Total)	
																		T ₄ (Free)	
		X																T ₄ (Total)	
																		Tacrolimus	
																		Testosterone (Free)*	
																		Testosterone (Total)	
															X			Theophylline	
																		Thyroglobulin	
																		TIBC	
																X		Tobramycin	
				X														Total hCG	
			X										X					Transferrin	
												X						Triglycerides	
																		Troponin I	
																		Troponin T	
																		TSH	
																		TT	
																		Tumour Necrosis Factor alpha (TNF-α)*	
				X														UIBC	U
												X						Unconjugated Oestriol	
												X						Urea	
																		Uric Acid	
																X		Urobilinogen	
															X			Valproic Acid	V
																X		Vancomycin	
																		Vascular Endothelial Growth Factor (VEGF)*	
																		Vitamin B12	
																		VMA	
																		Total White Blood Cell Count (WBC)	W
																		Zinc	Z

+ = Not accredited

* = Pilot study ongoing

PURPLE = The only parameters available on RQ9135/a

^a Pilot status only in certain programmes. Please check pages 42-46 for more information.

RANDEX QC PORTFOLIO

Our expertise in Quality Control have led to us creating market leading products that are tried and trusted by laboratory professionals. Our product portfolio offers high quality diagnostic solutions which offer reliable and rapid diagnosis and we believe that by providing laboratories with these tools, we can improve health worldwide.



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- ▶ Uniquely combining more than 100 analytes conveniently in a single control, laboratories can significantly reduce costs and consolidate without compromising on quality. As true third party controls, unbiased performance assessment with any instrument or method is guaranteed.



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Whilst every attempt is made to ensure that information is accurate and up-to-date, some information is subject to change.
Please contact marketing@randox.com for current details.



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ENGLISH

GLYCATED HAEMOGLOBIN (HbA1c) PROGRAMME: RQ9129

CONFIRMATION OF KIT CHARACTERISTICS AND RECEIPT DATE

Please confirm that the correct number of samples are present and that your samples have the appearance as indicated in the CHARACTERISTICS section below. Please confirm that none of the vials are broken and notify your local Randox representative immediately if there are any discrepancies. Finally, please log on to www.riqas.net to confirm the exact date on which you received this kit.

CHARACTERISTICS

The pack contains 6 vials of lyophilised 0.5 ml samples. The vials are labelled with the sample number.

PREPARATION/STORAGE/STABILITY OF SAMPLES

The samples are sealed under vacuum. Open the vial very carefully, avoiding any loss of material and reconstitute with an accurately measured 0.5ml volume of freshly distilled water at +20°C to +25°C. Replace the sample bottle cap, swirl the bottle several times and leave to stand at room temperature for 15 minutes. After 15 minutes, coat all surfaces of the bottle by rotating and inverting the bottle. Continue mixing until the solution is homogeneous and all lyophilised material is reconstituted. Do not shake the vial. The reconstituted sample should be analysed within 2 days. Do not freeze the reconstituted samples. The samples should be stored at 2 to 8°C when not in use.

NB. The reconstituted samples should be treated the same as patient samples. Depending on the method of analysis, they may require pre-treatment (either on the analyser, or manually) in order to assay for HbA1c.

Please note that although native material is used in this programme, the sample preparation and stabilization processes utilized may lead to the potential for non-commutability across all platforms. Performance evaluation should therefore be made against your registered peer group only.

SAFETY

Potentially Biohazardous Material. The samples contain human blood. Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

For **IN VITRO** use only, do not pipette by mouth, exercise the normal precautions required for handling laboratory reagents.

*** IMPORTANT NOTE:** Results must arrive at **RIQAS** by **17:00 hrs GMT** on the **FINAL DATE**. If the **RECOMMENDED ANALYSIS DATE** gives insufficient time, we suggest that the sample is analysed earlier to ensure you meet the deadline. Late results will not be accepted after the final date for the next sample.

GLYCATED HAEMOGLOBIN (HbA1c) PROGRAMME / PROGRAMME HEMOGLOBINE GLYQUEE (HbA1c) /
 PROGRAMMA EMOGLOBINA GLICATA (HbA1c) / PROGRAMA DE HEMOGLOBINA GLICOSILADA (HbA1c) /
 HEMOGLOBINA GLICADA (HbA1c) PROGRAMA / GLYCATED HAEMOGLOBIN (HbA1c) PROGRAM /
 PROGRAM DO OZNACZANIA HEMOGLOBINY GLIKOWANEJ (HbA1c) / CHU'ONG TRÌNH NGOẠI KIỂM (HbA1c) /
 GLIKOLIZE HEMOGLOBIN (HbA1c) PROGRAMI

RETURN OF RESULTS / DATES de RETOUR / INVIO DEI RISULTATI / ENVIO DE RESULTADOS
 PLAN FOR INSENDELSE AF / ZWROTU WYNIKÓW / GŪI TRẢ KẾT QUẢ / SONUÇ GÖNDERİM TARİHLERİ / ODOSLANIE VÝSLEDKOV

CYCLE 1B / CICLO 19B / RESULTATER 19B / CYKL 19B / CHU KỶ 19B / DÖNEM 19B / CYKLUS 19B

SAMPLE NO / ECHANTILLON NO, / N. CAMPIONE / N° DE MUESTRA / AMOSTRA N° / PRØVENR. / PROV NR. / MẪU SỐ ØRNEK NO / Č.VZORKY	RECOMMENDED ANALYSIS DATE / DATE RECOMMANDE POUR L' ANALYSE/ DATA DI ANALISI RACCOMANDATA / FECHA DE ANALISIS RECOMENDADA / DATA RECOMENDADA PARA ANÁLISE / ANBEFALET ANALYSEDATO / ZALECANA DATA WYKONANIA OZNACZENIA / NGÀY KHUYẾN CẢO PHẦN TÍCH ÖNERİLEN ANALİZ TARİHİ / ODPORÚČANÝ DATUM ANALÝZY	* FINAL DATE / *DATE LIMITE / * DATA FINALE / *FECHA FINAL / * DATA FINAL / * SLUTDATO / SIDSTE DATO * SLUTDATUM / * HẠN CUỐI GỬI TRẢ KẾT QUẢ *SON SONUÇ GÖNDERİM TARİHİ / *FINÁLNY DATUM
7	08.07.2024	15.07.2024
8	12.08.2024	19.08.2024
9	09.09.2024	16.09.2024
10	14.10.2024	21.10.2024
11	11.11.2024	18.11.2024
12	09.12.2024	16.12.2024

FRANÇAIS

PROGRAMME HEMOGLOBINE GLYQUEE (HbA1c): RQ9129

CONFIRMATION DES CARACTERISTIQUES DU KIT ET DE LA DATE DE RECEPTION:

Veuillez vérifier que l'ensemble des échantillons soient présents dans le coffret et que leur apparence est conforme comme indiqué dans la section ci-dessous. De plus assurez-vous qu'aucun des flacons ne soient brisés et en informer immédiatement votre représentant Randox si cela est le cas. Enfin, il est nécessaire de se connecter à www.riqas.net pour confirmer la date exacte à laquelle vous avez reçu ce kit.

CARACTÉRISTIQUES:

Ce coffret contient 6 sérums lyophilisés en flacons de 0.5 ml, étiquetés 1 à 6.

PREPARATION/STOCKAGE/STABILITE DES ECHANTILLONS

Les flacons sont scellés sous vide. Ouvrir avec précaution le flacon en évitant toute perte de matériel et reconstituer avec 0.5 ml d'eau distillée à une température comprise entre +20 et +25 °C. Remplacer le bouchon, agiter délicatement le flacon plusieurs fois et laisser reposer 15 minutes à température ambiante. Après 15 minutes, procéder à plusieurs retournements afin d'obtenir une solution homogène et s'assurer que tout le matériel lyophilisé soit dissout. Ne pas agiter le flacon. Une fois le flacon reconstitué, l'analyse des paramètres doit être réalisée dans les deux jours. Ne pas congeler les échantillons reconstitués. Les échantillons doivent être conservés entre 2-8 °C lorsqu'ils ne sont pas utilisés.

NB. Le contrôle reconstitué doit être traité comme un échantillon patient. Le pré-traitement dépend de votre méthode d'analyse, se référer à votre protocole.

Veuillez noter que bien que du matériel natif soit utilisé dans ce programme, les processus de préparation et de stabilisation des échantillons utilisés peuvent entraîner un risque de non-commutabilité sur toutes les plates-formes. L'évaluation des performances doit donc être effectuée uniquement par rapport à votre groupe de pairs.

SÉCURITÉ

Produit à risque biologique. Les échantillons contiennent du sang humain. Les donneurs du matériel source, dont ce produit a été dérivé, ont été testés pour la présence d'anticorps de l'Human Immunodeficiency Virus (HIV 1, HIV 2), l'antigène de surface de l'Hépatite B (HbsAg), et d'anticorps du virus de l'Hépatite C (HCV) et ont été trouvés NÉGATIFS. Ces tests ont été effectués par des méthodes approuvées par la FDA (US Food and Drug Administration). Cependant, aucun test ne pouvant apporter une garantie totale sur le caractère non infectieux de ces produits, il est recommandé de les manipuler et de les détruire selon les précautions requises pour tout matériel à risque biologique.

A usage **IN VITRO** exclusivement. Ne pas pipeter avec la bouche. Appliquer les précautions d'usage recommandées pour les manipulations des réactifs en laboratoire.

*** NOTE IMPORTANTE:** Les résultats **RIQAS** doivent parvenir au Département **RIQAS** au plus tard le lundi midi selon la **DATE FINALE**. Nous vous recommandons d'analyser les échantillons quelques jours avant la date finale. Les résultats en retard ne seront pas acceptés après la date finale de l'échantillon suivant. Vous pouvez envoyer vos résultats via Riqasnet ou par e.mail à l'adresse suivante: mail@riqas.com.

ITALIANO

PROGRAMMA EMOGLOBINA GLICATA (HbA1c): RQ9129

CONFERMA DELLE CARATTERISTICHE DEL KIT E DELLA DATA DI RICEZIONE

Si prega di confermare che sia presente il numero corretto di campioni e che i vostri campioni siano come indicato nella sezione CARATTERISTICHE qui sotto. Confermare che nessuna fiala sia rotta ed informare immediatamente il rappresentante Randox locale se ci fossero delle discrepanze. Infine, si prega di accedere al sito www.riqas.net per confermare la data esatta in cui si è ricevuto questo kit.

CARATTERISTICHE

La confezione contiene 6 fiale da 0.5 ml di campioni liofilizzati. Le fiale sono etichettate con il numero del campione.

PREPARAZIONE/CONSERVAZIONE/ STABILITA' DEI CAMPIONI

I campioni sono stati sigillati sotto vuoto. Aprire la fiala con estrema cautela, evitando qualsiasi fuoriuscita di materiale e ricostituire con un volume accuratamente misurato di 0.5ml di acqua appena distillata a +20 °C - +25 °C. Richiudere avvitando il tappo della confezione, roteare il flacone più volte e lasciare riposare a temperatura ambiente per 15 minuti, passati i quali, ruotando e mettendo sottosopra il flacone, fare in modo che le superfici interne ne siano del tutto rivestite. Continuare a miscelare sino a che la soluzione appaia omogenea e tutto il materiale liofilizzato sia ricostituito. Non agitare la fiala. Analizzare i vostri campioni entro 2 giorni dalla ricostituzione. Non congelare i campioni ricostituiti. I campioni, se non utilizzati, devono essere conservati a 2 - 8 °C.

NB. I campioni ricostituiti dovrebbero essere trattati allo stesso modo di quelli dei pazienti. In base al metodo analitico, potrebbe essere richiesto un pre-trattamento (o sull' analizzatore o manualmente) per poter effettuare la misurazione dell' HbA1c.

Si noti che sebbene in questo programma venga utilizzato materiale nativo, i processi di preparazione e stabilizzazione del campione utilizzati potrebbero portare alla potenziale non commutabilità su tutte le piattaforme. La valutazione delle prestazioni dovrebbe quindi essere effettuata solo rispetto al peer group registrato

SICUREZZA

Materiale potenzialmente pericoloso. I campioni contengono sangue umano. Il materiale di origine umana dal quale deriva il prodotto è stato controllato, relativamente al donatore, per l'eventuale presenza degli anticorpi da Virus da Immunodeficienza acquisita (HIV 1, HIV 2), antigene di superficie dell'Epatite B (HbsAg) ed anticorpi da virus dell'Epatite C(HCV) e trovato NON REATTIVO. Nell'esecuzione di tali prove sono stati utilizzati metodi approvati dall'FDA. Comunque, dal momento che nessun metodo può offrire la totale sicurezza dell'assenza di agenti infettivi, tale materiale ed i campioni dei pazienti devono essere maneggiati come fossero in grado di trasmettere malattie infettive e quindi smaltiti di conseguenza.

Per l'esclusivo uso **IN-VITRO**, non pipettare con la bocca e mettere in atto le normali precauzioni richieste nel maneggiare reagenti di laboratorio.

*** NOTA IMPORTANTE:** I risultati devono arrivare a **RIQAS** entro le **17:00 GMT** dell' **ULTIMA DATA**. Se la **DATA RACCOMANDATA PER L'ANALISI** non fornisce tempo a sufficienza, suggeriamo di analizzare il campione prima per essere certi di rispettare la scadenza. Risultati in ritardo non saranno accettati dopo l'ultima data del campione successivo.

PROGRAMA DE HEMOGLOBINA GLICOSILADA (HbA1c): RQ9129

CONFIRMACION DE LAS CARACTERISTICAS DEL KIT Y LA FECHA DE RECEPCION.

Por favor, Asegúrese de que ha recibido el numero correcto de muestras y que estas cumplen con la presentación indicada en la sección "CARACTERISTICAS" que encontrara a continuación. Por favor, confirme que ninguna de las muestras ha resultado dañada y contacte a su Representante local de Randox inmediatamente en el caso de que hubiese alguna discrepancia. Por ultimo, Acceda a www.riqas.net para confirmar la fecha exacta en la que recibió el kit.

CARACTERÍSTICAS

El paquete contiene 6 frascos de muestras liofilizadas de 0.5 ml. Las etiquetas de los frascos indican el número de muestra

PREPARACIÓN/ ALMACENAMIENTO/ ESTABILIDAD DE LAS MUESTRAS

Las muestras están selladas al vacío. Abrir el frasco con mucho cuidado, para evitar cualquier pérdida de material y reconstituir con una medida muy precisa de 0.5 ml de agua destilada recientemente y conservada entre +20°C y +25°C. Remplace el tapón de la botella, reestandarícela varias veces a temperatura ambiente y déjela reposar durante 15 minutos. Transcurridos los 15 minutos, recubra todas las superficies interiores de la botella rotándola e invirtiéndola. Continúe mezclándola hasta que la solución esté homogénea y se haya reconstituido todo el material liofilizado. No agite el vial. Por favor, analice las muestras dentro de los 2 días posteriores a su reconstitución. No congele las muestras reconstituidas. Las muestras deben refrigerarse a 2-8 °C cuando no estén en uso.

Nota. Las muestras reconstituidas deberían ser tratadas como las muestras de pacientes en el método de análisis pudiese requerir pre-tratamiento (en el autoanalizador, o manual) para informar sobre el porcentaje de HbA1c.

Tenga en cuenta que, aunque se utiliza material nativo en este programa, los procesos de preparación y estabilización de muestras utilizados pueden dar lugar a la posibilidad de no conmutabilidad en todas las plataformas. Por lo tanto, la evaluación del desempeño debe realizarse solo contra su grupo de pares registrado.

SEGURIDAD

Material potencialmente biopeligroso. Estas muestras contienen sangre humana. EL material Humano del que se deriva este producto, ha sido examinado a nivel de donante en cuanto a su reacción frente a anticuerpos del Virus de la Inmunodeficiencia Humana (HIV 1, HIV 2) , frente al Antígeno de Superficie de la Hepatitis B (HbsAg), y a Anticuerpos frente al Virus de la Hepatitis C (HCV) y se han encontrado NO-REACTIVOS., por métodos de ensayo aprobados por la FDA. Sin embargo, dado que ningún método de análisis puede ofrecer completa certeza sobre la ausencia de agentes infecciosos, este material y todas las muestras de pacientes, deberían ser tratadas como potencialmente infecciosas y desechados de forma consecutiva.

Par el uso exclusivo de **IN VITRO**, no pipetear con la boca. Ejercite las precauciones normales requeridas para tratar reactivos de laboratorio.

*** NOTA IMPORTANTE:** Los resultados deben arribar a **RIQAS** a las **17:00 horas GMT** en la **FECHA FINAL**. Si la **FECHA RECOMENDADA PARA ANALISIS** dada es insuficiente, le sugerimos que analice la muestra antes para asegurarse que la tenga lista en la fecha final. Los resultados tardíos nos serán aceptados después de la fecha final de la siguiente muestra.

PORTUGUÊS

HEMOGLOBINA GLICADA (HbA1c) PROGRAMA: RQ9129

CONFIRMAÇÃO DAS CARACTERÍSTICAS DO KIT E DATA DE RECEPÇÃO

Agradecemos-lhe que confirme que recebeu o número correcto de amostras e que estas têm o aspecto descrito na secção CARACTERÍSTICAS deste documento. Verifique também, se nenhum dos frascos está partido e notifique o seu representante local da Randox caso encontre alguma discrepância. Finalmente, acceda ao www.riqas.net para confirmar a data exacta em que recebeu este kit.

CARACTERÍSTICAS

A embalagem contém 6 frascos de 0.5 ml de amostras liofilizadas. Os frascos encontram-se rotulados com o número de amostra.

PREPARAÇÃO/CONSERVAÇÃO/ESTABILIDADE DAS AMOSTRAS

As amostras são seladas sob vácuo. Abrir o frasco cuidadosamente, evitando perda de material e reconstituir com o volume preciso de 0.5 ml de água destilada de +20°C a +25°C. Colocar a tampa no frasco, rodar suavemente o frasco várias vezes e deixar em repouso à temperatura ambiente por 15 minutos. Depois de 15 minutos, molhar a superfície do frasco rodando-o e invertendo-o. Continuar a misturar até que a solução esteja homogénea e todo o material liofilizado esteja reconstituído. Não agitar o frasco. Por favor analise as suas amostras dentro de 2 dias após reconstituição. Não congelar as amostras reconstituídas. As amostras devem ser conservadas de 2-8 °C quando não estão a ser usadas.

NB. As amostras reconstituídas devem ser tratadas da mesma forma que as amostras de doentes. Dependendo de método de análise, podem requerer pré-tratamento (tanto no analisador como manualmente) para ensaiar a HbA1c.

Tenha por favor em consideração que apesar ser usado material nativo neste programa, os processos de estabilização e preparação da amostras podem levar a potencial não-comutabilidade entre todas as plataformas. A avaliação de desempenho deve por isso ser feita somente em comparação com o seu grupo paritário.

SEGURANÇA

Material potencialmente nocivo biologicamente. As amostras contém sangue humano. A fonte humana de onde este produto foi obtido foi testada ao nível do dador quanto ao anticorpo do Vírus da Imunodeficiência Humana (HIV 1, HIV 2), Antígeno de superfície Hepatite B (HbsAg), e anticorpo do Vírus da Hepatite C (HCV) e detectou-se ser NÃO -REACTIVO Foram usados métodos aprovados pela FDA para conduzir estes testes. No entanto, uma vez que nenhum método pode oferecer garantia total quanto a ausência de agentes infecciosos, este material, bem como as amostras de doentes, devem ser manuseados como sendo capazes de transmitir doenças infecciosas.

Para utilização exclusiva **IN VITRO**, não pipetar com a boca, respeitar as precauções normais necessárias para manuseamento de reagentes de laboratório.

*** NOTA IMPORTANTE:** Os resultados devem chegar ao **RIQAS** na **DATA FINAL** até às **17 horas, GMT**. Se a **DATA RECOMENDADA PARA ANÁLISE** não permitir tempo suficiente para o envio, sugere-se que a amostra seja ensaiada antecipadamente, de forma a garantir o cumprimento do prazo final. Os resultados em atraso não serão aceites após a data final da amostra seguinte.

POLSKI

PROGRAM DO OZNACZANIA HEMOGLOBINY GLIKOWANEJ (HbA1c) : RQ9129

POTWIERDZENIE CHARAKTERYSTYKI ZESTAWU I DATY ODBIORU

Prosimy o potwierdzenie, że zestaw zawiera odpowiednią ilość próbek i Państwa próbki wyglądają tak, jak w podanej poniżej CHARAKTERYSTYCE. Prosimy o potwierdzenie, że żadna z próbek nie jest zbita, a jeśli są jakiegokolwiek niezgodności prosimy o niezwłoczne zgłoszenie tego lokalnemu przedstawicielowi.

Następnie prosimy o zalogowanie się na www.riqas.net w celu potwierdzenia dokładnej daty otrzymania zestawu.

CHARAKTERYSTYKA

Opakowanie zawiera 6 fiolek próbek liofilizowanych po 0.5 ml. Fiolki są oznakowane numerem próbek.

PRZYGOTOWANIE/PRZECHOWYWANIE/STABILNOŚĆ PRÓBEK

Próbki są zamknięte metodą próżniową. Otworzyć fiolkę bardzo ostrożnie, unikając utraty materiału i rekonstruować w dokładnie odmierzonej objętości 0.5 ml świeżo destylowanej wody w temperaturze od +20 do +25°C. Zamknąć fiolkę korkiem, zamieszać kilka razy i pozostawić na 15 minut w temperaturze pokojowej. Po 15 minutach pokryć wszystkie powierzchnie butelki poprzez obracanie i odwracanie butelki. Kontynuować mieszanie dopóki roztwór nie będzie jednorodny i całkowicie rozpuszczony cały materiał liofilizowany. Nie wstrząsać fiolką. Prosimy wykonać oznaczenie nie później niż w ciągu dwóch dni od przygotowania materiału. Nie zamrażać zrekonstruowanej próbki. Próbkę, kiedy nie są w użyciu powinny być przechowywane w temperaturze 2-8 °C.

UWAGA. Zrekonstruowane próbki zaleca się traktować tak samo jak materiał pobrany od pacjentów. W zależności od metody oznaczania próbek, może być wymagane wstępne przygotowanie próbki (przy użyciu analizatora bądź manualnie) w celu oznaczenia HbA1c.

Należy pamiętać, że chociaż w tym programie wykorzystywany jest materiał natywny, procedura przygotowania i stosowane procesy stabilizacji próbki mogą prowadzić do niezmienności na wszystkich platformach. Ocena wyników powinna być zatem dokonywana wyłącznie w odniesieniu do zarejestrowanej grupy porównawczej.

BEZPIECZEŃSTWO

Materiał potencjalnie szkodliwy biologicznie. Próbki zawierają krew ludzką. Materiały pochodzenia ludzkiego, z których pochodzi ten produkt, były badane pod względem obecności przeciwciał przeciwko wirusowi ludzkiego niedoboru odporności (HIV 1, HIV 2), antygenowi powierzchniowego wirusa zapalenia wątroby typu B (Hbs Ag) oraz przeciwciał przeciwko wirusowi zapalenia wątroby typu (HCV) i zostały uznane za NIE-REAKTYWNE. W celu przeprowadzenia tych testów zastosowano metody zatwierdzone przez FDA. Ponieważ żadna metoda nie daje całkowitej pewności nieobecności czynników zakaźnych, dlatego ten materiał i wszystkie próbki od pacjentów powinny być traktowane jako potencjalne źródło chorób zakaźnych i usuwane w odpowiedni sposób.

Tylko do **IN VITRO**, nie pipetować ustami, zachować ostrożność wymaganą przy używaniu odczynników laboratoryjnych.

* **UWAGA:** Wyniki muszą dotrzeć do **RIQAS** do godziny **17:00 czasu GMT w dniu DATY FINALNEJ**. Jeżeli **ZALECANA DATA OZNACZENIA** jest zbyt późna, sugeruje się przeprowadzenie wcześniejszej analizy, aby uzyskać czas na przesłanie wyników. Spóźnione wyniki przesłane po dacie finalnej następnej próbki nie zostaną przyjęte.

TIẾNG VIỆT

CHƯƠNG TRÌNH NGOẠI KIỂM HbA1c: RQ9129

XÁC NHẬN VỀ NHỮNG ĐẶC TÍNH MẪU VÀ NGÀY NHẬN

Xin vui lòng xác nhận rằng bạn đã nhận đúng và đầy đủ số lượng mẫu, những mẫu đó được mô tả như phần "ĐẶC TÍNH" dưới đây. Xin vui lòng xác nhận không có lọ mẫu nào bị vỡ hoặc hư hỏng và thông báo ngay cho đại diện của hãng Randox tại địa phương của bạn nếu có sai lệch. Sau cùng, xin vui lòng đăng nhập vào www.riqas.net để xác nhận thời gian chính xác mà bạn đã nhận bộ mẫu này.

ĐẶC ĐIỂM

1 hộp bao gồm 6 lọ mẫu dạng đồng khô, mỗi lọ 0.5 ml (6 x 0.5 ml) được đánh số thứ tự từ 1-6 theo số thứ tự mẫu phân tích

CHUẨN BỊ/BẢO QUẢN/ĐỘ BỀN CỦA MẪU

Lọ mẫu được đóng nắp chân không. Mở nắp lọ cẩn thận tránh làm thất thoát, pha loãng với chính xác 0.5ml nước cất hai lần ở **+20°C - +25°C**. Đậy nắp cao su và lắc nhẹ nhàng sau đó để mẫu yên ở nhiệt độ phòng trong 15 phút. Sau 15 phút, đảo đều lọ mẫu để mẫu hòa tan hoàn toàn tạo dung dịch đồng nhất. Chú ý không được lắc mạnh. Khuyến cáo phân tích mẫu trong vòng 2 ngày sau khi hoàn nguyên. Không được đông lạnh mẫu đã hoàn nguyên. Những mẫu này nên được bảo quản ở nhiệt độ 2-8 °C khi chưa sử dụng

Chú ý: Mẫu phân tích sau khi hoàn nguyên được xử lý giống như mẫu bệnh nhân. Tùy thuộc vào phương pháp phân tích, mẫu có thể phải tiền xử lý (ly giải hồng cầu) trước khi phân tích HbA1c

Xin lưu ý rằng mặc dù vật liệu gốc được sử dụng trong chương trình này nhưng quy trình chuẩn bị mẫu và độ ổn định có thể dẫn đến những khả năng mẫu không tương đồng với mẫu bệnh nhân trên tất cả các thiết bị. Do đó, hiệu suất chỉ được đánh giá với nhóm đồng đẳng mà phòng xét nghiệm đã đăng ký.

ĐỘ AN TOÀN

Có khả năng độc hại về sinh học. Mẫu chứa thành phần từ máu người và đều được kiểm tra âm tính với HIV-1, HIV-2, HCV, HbsAg theo phương pháp được FDA chứng nhận. Tuy nhiên để bảo đảm an toàn tuyệt đối nên mẫu này nên được xử lý như mẫu bệnh nhân để tránh lây nhiễm.

Chỉ dùng cho phân tích trong ống nghiệm. Không được hút mẫu bằng miệng. Tuân thủ các khuyến cáo thông thường yêu cầu trong quy trình xử lý hoá chất phòng xét nghiệm.

LƯU Ý QUAN TRỌNG:

Kết quả phân tích phải được gửi đến cho RIQAS trước 17:00 GMT ngày hạn chót gửi trả kết quả. Phòng xét nghiệm nên phân tích mẫu sớm trước ngày khuyến cáo phân tích mẫu nếu cần để đảm bảo thời gian gửi trả kết quả. Kết quả phân tích trễ sẽ không được chấp nhận sau hạn chót gửi trả kết quả của mẫu tiếp theo.

KİT ÖZELLİKLERİNİN VE ULAŞMA TARİHİNİN DOĞRULANMASI

Lütfen doğru sayıda örneğin bulunduğunu ve örneklerin görünüşlerinin aşağıda ÖZELLİKLER bölümünde belirtildiği gibi olduğunu doğrulayınız. Lütfen şişelerden hiç birinin kırık olmadığını doğrulayınız ve eğer herhangi bir uygunsuzluk varsa derhal yerel RANDOX sorumlunuzu uyarınız. Son olarak, lütfen www.riqas.net 'e giriş yaparak bu kiti hatasız teslim aldığınız tarihi doğrulayınız.

ÖZELLİKLER

Paket; 6 şişe 0.5 ml'lik liyofilize örnekten oluşmaktadır. Şişeler, örnek numaralarıyla etiketlenmiştir.

NUMUNE HAZIRLAMA / DEPOLAMA / NUMUNELERİN STABİLİTESİ

Örnekler vakumlanarak ambalajlanmıştır. Şişeyi, herhangi bir materyal kaybı olmayacak şekilde dikkatlice açınız ve kalibre edilmiş bir pipetle tam 0.5 ml'lik hacimde taze distile su ile +20°C - +25°C'de sulandırınız. Plastik kapağı yerleştiriniz, şişeyi kapatınız, şişeyi bir kaç kez alt üst ediniz ve 15 dakika oda ısısında bekletiniz. 15 dakika sonra, distile suyun tüm yüzeylerle temasını sağlamak için şişeyi hafifçe çeviriniz ve alt üst ediniz. Solüsyon homojen hale gelinceye ve liyofilize materyal tamamen çözünene kadar karıştırmaya devam ediniz. Şişeyi hafifçe alt-üst ederek liyofilize materyalin tamamen çözündüğünden emin olunuz. Çalkalamayınız. Lütfen, örneği çözdükten sonraki 2 gün içerisinde çalışınız. Çözünmüş örnekleri dondurmayınız. Örnekler kullanılmadığı zaman 2-8°C'de muhafaza edilmelidir.

NOT. Çözünmüş örneklerle, hasta örnekleriyle aynı şekilde muamele edilmelidir. Analiz metoduna bağlı olarak HbA1c analizi için örneklerle ön-işlem gerekebilir (analizör üzerinde veya manuel).

Bu programda yerel malzeme kullanılmasına rağmen kullanılan numune hazırlama ve stabilizasyon işlemlerinin tüm platformlarda değiştirilemezlik potansiyeline yol açabileceğini lütfen unutmayın. Bu nedenle performans değerlendirmesi, yalnızca kayıtlı akran grubunuza göre yapılmalıdır.

GÜVENLİK

Potansiyel olarak biyolojik tehlikeli madde. Örnekler insan kanı içerir. Bu ürünün elde edildiği insan kaynaklı materyal donör seviyesinde İnsan İmmünyetmezlik Virüsü (HIV 1, HIV 2) antikor, Hepatit B yüzey Antijeni (HbsAg), ve Hepatit C Virüs (HCV) antikor açısından test edilmiş ve NON-REAKTİF olarak bulunmuştur. Bu testler için FDA onaylı metotlar kullanılmıştır. Fakat yine de, hiç bir metot enfeksiyon ajanlarının yokluğu için tam garanti veremediğinden bu materyal ve tüm hasta örnekleri muhtemel enfeksiyon hastalığı taşıyıcısı varsayılarak çalışılmalı ve uygun şekilde atığa gönderilmelidir.

Sadece IN VITRO kullanım içindir. Ağızla pipetleme yapmayınız. Laboratuvar reaktiflerinin örneklenmesi için gerekli normal önlemleri uygulayınız.

*** ÖNEMLİ NOT:** Sonuçlar, RIQAS'a **SON SONUÇ GÖNDERİM TARİHİ**'nde saat 17:00'de ulaşılmış olmalıdır. Eğer **ÖNERİLEN ANALİZ TARİHİ** sizin için uygun değilse, sonuç gönderim tarihine yetişişi için için örneği daha erken analiz etmenizi öneririz. Geç sonuçlar, bir sonraki örneğin son sonuç gönderim tarihi sonrasında kabul edilmeyecektir.

SLOVENSKY

GLYCATED HAEMOGLOBIN (HbA1c) PROGRAMME: RQ9129

POTVRDENIE CHARAKTERISTIKY KITU A DÁTUMU DORUČENIA

Prosím potvrdte doručenie správneho čísla vzorky a potvrdte, či vzhľad vzoriek zodpovedá charakteristike opisanej v sekcii nižšie. Prosím potvrdte, že žiadne fľaštičky nie sú rozbité, v opačnom prípade okamžite kontaktuje svojho obchodného zástupcu. Po prihlásení na www.riqas.net potvrdte a zadajte presný dátum, kedy Vám bol kit doručený.

CHARAKTERISTIKA

Balenie obsahuje 6 fľaštičiek lyofilizovaných 0.5 ml vzoriek. Fľaštičky sú označené číslom vzorky.

PRÍPRAVA/SKLADOVANIE/STABILITA VZORIEK

Fľaštička je vákuovo uzatvorená. Otvorte fľaštičku veľmi opatrne, vyhnite sa stratám materiálu a použitím **nakalibrovannej pipety** rekonštituujte presne **0.5 ml** objemu čerstvo destilovanej vody pri teplote **+20°C to +25°C**. Zatvorte fľaštičku, niekoľko krát jemne premiešajte a nechajte odstáť pri izbovej teplote **15 minút**. Po 15 minútach vytvorené vrstvy odstráňte rotáciou a prevracaním fľaštičky. Pokračujte v miešaní kým nebude roztok homogénny a všetok lyofilizovaný materiál rekonštituovaný. Neترaste fľaštičkou. Vzorky analyzujte do 2 dní po rekonštitúcii. Rekonštituované vzorky nezmrazujte. Vzorky skladujte pri teplote 2 - 8°C.

Poznámka: So vzorkami zaobchádzajte rovnakým spôsobom ako s patientskými vzorkami. V závislosti od metódy analýzy, môže byť požadovaná úprava vzoriek (analýzátorom alebo manuálne).

Upozorňujeme, že hoci sa v tomto programe používa natívny materiál, použité procesy prípravy a stabilizácie vzoriek môžu viesť k potenciálnej nekomutabilite na všetkých platformách.

Hodnotenie výkonu by sa preto malo vykonávať iba vo vzťahu k vašej zaregistrovanej skupine porovnania.

BEZPEČNOST

Potenciálne nebezpečný materiál. Vzorky obsahujú ľudskú krv. Materiál ľudského pôvodu, ktorý bol testovaný na HIV (HIV 1 a HIV2) protilátky, HBsAg a hepatitídu C (HCV) a bol NEREAKTÍVNY. Avšak žiadna metóda nedokáže zabezpečiť absolútnu istotu pri detekcii, preto s týmto materiálom a všetkými patientskými vzorkami by sa malo zaobchádzať ako by boli schopné prenášať infekčné ochorenie.

Iba na **IN VITRO** použitie, nepipetujte ústami, vykonajte bežné bezpečnostné opatrenia vyžadované pri laboratórnych postupoch.

*** POZNÁMKA:** Výsledky musia byť odoslané do **RIQAS** do **17:00 Hod GMT** vo **FINÁLNY DÁTUM**. Ak **ODPORÚČANÝ DÁTUM ANALÝZY** neposkytuje dostatočný čas, odporúčame analýzu vzorky skôr, aby sa zabezpečilo dodržanie termínu. Výsledky prijaté po finálnom termíne nebudú akceptované.

ENGLISH
SEROLOGY (HIV/HEPATITIS): RQ9151

CONFIRMATION OF KIT CHARACTERISTICS AND RECEIPT DATE

Please confirm that the correct number of samples are present and that your samples have the appearance as indicated in the CHARACTERISTICS section below. Please confirm that none of the vials are broken and notify your local Randox representative immediately if there are any discrepancies. Finally, please log on to www.riqas.net to confirm the exact date on which you received this kit.

CHARACTERISTICS

24 samples are supplied per cycle and are shipped in packs of 12. The pack contains 12 vials of liquid material (12 x 1.8 ml). The vials are labelled with the sample number.

PREPARATION/STORAGE/STABILITY OF SAMPLES

Allow control to come to room temperature. Ensure the samples are homogeneous by swirling gently, do not shake the vials. To avoid evaporation, close vial immediately after use and store at +2 to +8°C. The samples should be treated in the same way as patient samples. Once opened please analyse the samples within 2 days.

SAFETY

Biological source material. Treat as potentially infectious.

Each human serum or plasma donor unit used in the preparation of this product has been tested for the presence of HBsAg, antibodies to HIV-1 and HIV-2 and antibodies to HCV using licensed reagents. Human source materials reactive for viral hepatitis markers and antibodies to retroviruses used to produce this product have been treated to inactivate infectious agents. However, no known test method can assure that products derived from human sources will not transmit infection. It is recommended that this product and all human specimens be handled in accordance with Biosafety Level 2 practices as described in World Health Organization Laboratory Biosafety Manual, or other equivalent guidelines. For **IN VITRO** use only.

*** IMPORTANT NOTE:** Results must arrive at RIQAS by **17:00 HRS GMT** on the **FINAL DATE**. If the **RECOMMENDED ANALYSIS DATE** gives insufficient time, we suggest that the sample is analysed earlier to ensure you meet the deadline. Late results will not be accepted after the final date for the next sample.

SEROLOGY (HIV/HEPATITIS) / SIEROLOGIA (HIV/EPATITE) / SEROLOGIA (HIV/WZW) / SEROLOGIE (HIV/HEPATITE) /
 SEROLOGIA (HIV/HEPATITIS) / SEROLOGIA (HIV/HEPATITE) / 血清 (艾滋病病毒、肝炎) /
 CHƯƠNG TRÌNH NGOẠI KIỂM (HIV-HEPATITIS) / SEROLOJİ (HIV/HEPATITIS)

RETURN OF RESULTS / RETOUR DES RESULTATS / INVIO DEI RISULTATI/ ENVIO DE RESULTADOS /
 PRZESYŁANIE WYNIKÓW / 回复结果 / GÜİ TRÁ KÉT QUẢ / SONUÇ GÖNDERİM TARİHLERİ / ODOŠLANIE VÝSLEDKOV

CYCLE 12B / CICLO 12B / CIKLAS 12B / CYKL 12B / 返回结果周期 12B / CHU KỲ 12B / DÖNEM 12B / CYKLUS 12B

SAMPLE NO / ECHANTILLON NO. / N. CAMPIONE / N° DE MUESTRA / AMOSTRA N°. / NR PRÓBK / 样品号 / MŨU SỐ / ORNEK NO / Ć.VZORKY	RECOMMENDED ANALYSIS DATE/ DATE RECOMMANDE POUR L' ANALYSE/ DATA DI ANALISI RACCOMANDATA/ FECHA DE ANALISIS RECOMENDADA/ ZALECANA DATA WYKONANIA OZNACZENIA/ 推荐分析日期 NGÀY KHUYẾN CÁO PHÂN TÍCH / ÖNERİLEN ANALİZ TARİHİ / ODPORÚČANÝ DÁTUM ANALÝZY	* FINAL DATE/ *DATE LIMITE/ * DATA FINALE/ *FECHA FINAL/ * DATA KOŃCOWA/ *最终日期 * HẠN CUỐI GỬI TRẢ KẾT QUẢ/ * SON SONUÇ GÖNDERİM TARİHİ/ * FINÁLNÝ DÁTUM
13	01.01.24	08.01.24
14	01.01.24	08.01.24
15	29.01.24	05.02.24
16	29.01.24	05.02.24
17	26.02.24	04.03.24
18	26.02.24	04.03.24
19	25.03.24	01.04.24
20	25.03.24	01.04.24
21	29.04.24	06.05.24
22	29.04.24	06.05.24
23	27.05.24	03.06.24
24	27.05.24	03.06.24

SEROLOGIE (HIV/HEPATITE): RQ9151**CONFIRMATION DES CARACTERISTIQUES DU KIT ET DE LA DATE DE RECEPTION :**

Veuillez vérifier que l'ensemble des échantillons soient présents dans le coffret et que leur apparence est conforme comme indiqué dans la section CARACTERISTIQUES. De plus assurez-vous qu'aucun des flacons ne soient brisés et en informer immédiatement votre représentant Randox si cela est le cas, une photo sera demandée. Enfin, il est nécessaire de se connecter à www.rigas.net pour confirmer la date exacte à laquelle vous avez reçu ce kit.

CARACTERISTIQUES

24 échantillons sont fournis par cycle et sont expédiés dans des emballages de 12 flacons. Le coffret contient 12 flacons de matériel liquide (12 x 1.8 ml). Le numéro de l'échantillon est noté sur l'étiquette.

PREPARATION/STOCKAGE/STABILITE DES ECHANTILLONS

Avant le dosage, laissez le contrôle arriver à température ambiante. Vérifiez que les échantillons sont homogènes en remuant doucement, ne pas secouer les flacons. Pour éviter l'évaporation, fermer le flacon immédiatement après usage et le conserver entre +2 et + 8 ° C. Les échantillons doivent être traités de la même manière que les échantillons de patients. Une fois le flacon ouvert, les échantillons doivent être analysés dans les 2 jours.

SÉCURITÉ**Matériel de source biologique. Traiter comme potentiellement infectieux.**

Chaque préparation de sérum ou plasma provient de donneurs humains, a été testée pour détecter la présence de HBsAg, d'anticorps contre le VIH-1 et le VIH-2 et d'anticorps contre le VHC à l'aide de réactifs homologués.

Les matériaux d'origine humaine réactifs aux marqueurs viraux de l'hépatite et les anticorps contre les rétrovirus utilisés pour produire ce produit ont été traités pour inactiver les agents infectieux. Cependant, aucune méthode d'essai connue ne peut garantir que les produits dérivés de sources humaines ne transmettent pas l'infection. Il est recommandé que ce produit et tous les spécimens humains soient manipulés conformément aux pratiques de niveau 2 de biosécurité décrites dans le Manuel de biosécurité de laboratoire de l'Organisation mondiale de la Santé, ou à d'autres lignes directrices équivalentes

A usage **IN VITRO** seulement.

NOTE IMPORTANTE: Les résultats **RIQAS** doivent parvenir au Département **RIQAS** au plus tard le lundi 17h00 selon la **DATE FINALE**. Nous vous recommandons d'analyser les échantillons quelques jours avant cette date finale. Les résultats en retard ne seront pas acceptés après la date finale. Vous pouvez envoyer vos résultats via Rigasnet ou par e.mail à l'adresse suivante: mail@rigas.com.

ESPAÑOL**SEROLOGIA (HIV/HEPATITIS): RQ9151****CONFIRMACIÓN DE LAS CARACTERÍSTICAS DEL KIT Y LA FECHA DE RECEPCIÓN.**

Por favor, Asegúrese de que ha recibido el numero correcto de muestras y que estas cumplen con la presentación indicada en la sección "CARACTERISTICAS" que encontrara a continuación. Por favor, confirme que ninguna de las muestras ha resultado dañada y contacte a su Representante local de Randox inmediatamente en el caso de que hubiese alguna discrepancia. Por ultimo, acceda a www.rigas.net para confirmar la fecha exacta en la que recibió el kit.

CARACTERÍSTICAS

24 muestras son provistas para cada ciclo y enviadas en estuches de 12. Cada Paquete contiene 12 viales de material liquido (12 x 1.8ml). Los viales están etiquetados con el número de muestra.

PREPARACIÓN/ ALMACENAMIENTO/ ESTABILIDAD DE LAS MUESTRAS

Deje que el control llegue a temperatura ambiente. Asegúrese de que las muestras son homogéneas girando suavemente, no agite los viales. Para evitar la evaporación, cerrar el vial inmediatamente después de usar y almacenar entre +2 y +8°C. Todas las muestras se deben procesar juntas y los resultados devueltos a RIQAS en la fecha detallada a continuación. Las muestras deben ser tratados de la misma forma que las muestras de pacientes. Una vez abierto por favor, analizar las muestras dentro de 2 días

SEGURIDAD**Material de origen biológico. Tratar como potencialmente infeccioso.**

Todo el material de suero o plasma humano de donantes utilizado en la elaboración de este producto ha sido analizado para detectar la presencia de HBsAg, anticuerpos de HIV-1 y HIV-2 y anticuerpos de HCV utilizando reactivos autorizados. El material de origen humano positivo para marcadores virales de hepatitis y anticuerpos de retrovirus que se ha utilizado en la fabricación de este producto han sido tratados con tal de inactivar los agentes infecciosos. Sin embargo, ningún método puede garantizar que los productos derivados de material humano no transmitan la infección. Se recomienda que este producto y todas las muestras humanas se manipulen de acuerdo con las prácticas de Bioseguridad de Nivel 2 descritas en el Manual de Bioseguridad del Laboratorio de la Organización Mundial de la Salud u otras guías equivalentes.

Solo para uso en Vitro

*** NOTA IMPORTANTE:** Los resultados deben enviarse a RIQAS antes de las 17.00 Horas GMT de la fecha límite. Si piensan que no van a poder enviar los resultados antes de la fecha límite sugerimos analicen las muestras lo antes posible con la finalidad de poder enviar los resultados antes de la fecha indicada. Los resultados que se envíen después de la fecha límite no serán aceptados.

SIEROLOGIA (HIV EPATITE): RQ9151

CONFERMA DELLE CARATTERISTICHE DEL KIT E DELLA DATA DI RICEZIONE

Si prega di confermare che sia presente il numero corretto di campioni e che i vostri campioni siano come indicato nella sezione CARATTERISTICHE qui sotto. Confermare che nessuna fiala sia rotta ed informare immediatamente il rappresentante Randox locale se ci fossero delle discrepanze. Infine, si prega di accedere al sito www.riqas.net per confermare la data esatta in cui si è ricevuto questo kit.

CARATTERISTICHE

Sono forniti 24 campioni per ciclo e sono spediti in pacchi da 12. Il pacco contiene 12 fiale di materiale liquido (12 x 1.8 ml). Le fiale sono etichettate con il numero del campione.

PREPARAZIONE/CONSERVAZIONE/ STABILITA' DEI CAMPIONI

Attendere che il controllo raggiunga la temperatura ambiente. Assicurarsi che i campioni siano omogenei agitando leggermente, non scuotere le fiale. Per evitare l'evaporazione, chiudere la fiala immediatamente dopo l'uso e conservare a +2 - +8°C. I campioni devono essere manipolati come fossero campioni di pazienti. Una volta aperti analizzare i campioni entro 2 giorni

SICUREZZA

Materiale di origine biologica. Trattare come potenzialmente infettivo.

Ogni unità di donatore di siero o plasma umano utilizzata nella preparazione di questo prodotto è stata testata per la presenza di HBsAg, anticorpi HIV-1 e HIV-2 e anticorpi HCV utilizzando reagenti autorizzati. I materiali di origine umana reattivi per i marcatori dell'epatite virale e gli anticorpi contro i retrovirus usati per produrre questo prodotto sono stati trattati per inattivare gli agenti infettivi. Tuttavia, nessun metodo di prova noto può garantire che i prodotti derivati da fonti umane non trasmettano infezioni. Si consiglia di manipolare questo prodotto e tutti i campioni umani in conformità con le pratiche di Biosicurezza Livello 2 descritte nel Manuale sulla biosicurezza dei laboratori dell'Organizzazione mondiale della sanità, o altre linee guida equivalenti. Solo per uso **IN VITRO**.

*** NOTA IMPORTANTE:** I risultati devono arrivare a RIQAS entro le **17:00 HRS GMT della DATA FINALE**. Se la **DATA DI ANALISI RACCOMANDATA** non fornisce abbastanza tempo, suggeriamo di analizzare il campione prima per assicurare il rispetto della scadenza. Risultati in ritardo non saranno accettati dopo l'ultima data del campione successivo.

PORTUGUÊS

SEROLOGIA (VIH/HEPATITE): RQ9151

CONFIRMAÇÃO DAS CARATERÍSTICAS DO KIT E DATA DE RECEÇÃO

Agradecemos-lhe que verifique se que recebeu o kit contem o número correto de amostras e se estas têm o aspeto descrito na secção CARATERÍSTICAS. Confirme por favor se nenhum dos frascos está partido e notifique imediatamente o seu representante local da Randox se encontrar alguma discrepância. . correto de amostras e que estas têm o aspeto descrito na secção a seguir o documento. Verifique também, se nenhum dos frascos está partido e notifique o seu representante local da Randox caso encontre alguma discrepância. Finalmente, aceda ao www.riqas.net para confirmar a data exata em que rececionou este kit.

CARATERÍSTICAS

São fornecidas 24 amostras por ciclo. As amostras são enviadas em kits de 12 amostras. O kit inclui 12 frascos de material líquido (12 x 1.8ml). Os frascos estão identificados com o número da amostra.

PREPARAÇÃO/CONSERVAÇÃO/ESTABILIDADE DAS AMOSTRAS

Deixe o controlo estabilizar à temperatura ambiente. Verifique se as amostras estão homogêneas rodando-as suavemente, não agite os frascos. Feche o frasco imediatamente após a utilização e conserve de +2 a +8°C para evitar a evaporação. As amostras devem ser tratadas da mesma forma que as amostras de doentes. Uma vez abertas analisar as amostras dentro de 2 dias.

SEGURANÇA

Material de Origem Biológica. Trate como sendo potencialmente infeccioso.

Cada unidade dadora de soro ou plasma usada na preparação deste produto foi testada quanto à presença de HBsAg, anticorpos para VIH-1 e VIH-2 e anticorpos para VHC usando reagentes licenciados. As matérias primas humanas usadas para produzir este produto, reativas para marcadores de hepatite virais e anticorpos para retrovírus foram tratadas para inativar os agentes infecciosos. No entanto, nenhum método pode garantir que os produtos de origem humana não transmitam infeção. Recomenda-se que este produto, bem como todas as amostras humanas sejam manuseadas de acordo as práticas de Segurança Biológica Nível 2. Tal como o descrito no Manual de Segurança Biológica da Organização Mundial de Saúde, ou outras diretrizes equivalentes. Somente para utilização **IN VITRO**

*** NOTA IMPORTANTE:** Os resultados têm de chegar ao RIQAS até às **17:00 horas GMT da DATA FINAL**. Se a **DATA RECOMENDADA PARA ANÁLISE** não der tempo suficiente, sugerimos que a amostra seja analisada mais cedo para chegar a tempo. Os resultados atrasados não serão aceites após a data final da próxima amostra.

SEROLOGIA (HIV/WZW): RQ9151**POTWIERDZENIE CHARAKTERYSTYKI ZESTAWU I DATY ODBIORU**

Prosimy o potwierdzenie, że zestaw zawiera odpowiednią ilość próbek i Państwa próbki wyglądają tak, jak w podanej poniżej CHARAKTERYSTYCE. Prosimy o potwierdzenie, że żadna z próbek nie jest zbita, a jeśli są jakiegokolwiek niezgodności prosimy o niezwłoczne zgłoszenie tego lokalnemu przedstawicielowi. Następnie prosimy o zalogowanie się na www.riqas.net w celu potwierdzenia dokładnej daty otrzymania zestawu.

CHARAKTERYSTYKA

24 próbek jest dostarczanych w cyklu i wysyłanych w opakowaniach po 12. Opakowanie zawiera 12 próbek materiału płynnego (12 x 1.8 ml). Fiolki są oznakowane numerem próbek.

PRZYGOTOWANIE/PRZECHOWYWANIE/STABILNOŚĆ PRÓBEK

Prosimy poczekać na osiągnięcie przez materiał temperatury pokojowej. Prosimy upewnić się, że próbki są jednorodne poprzez delikatne obracanie próbek, nie wstrząsać fiolką. Aby zapobiec parowaniu należy zamknąć fiolkę natychmiast po użyciu i przechowywać w temperaturze od +2 do +8 °C. próbki powinny być traktowane w taki sam sposób jak próbki pacjentów. Po otwarciu należy oznaczyć próbki w ciągu 2 dni.

BEZPIECZEŃSTWO**Materiał biologiczny. Traktować jako potencjalnie zakaźny.**

Każdy dawca surowicy lub osocza użytego do przygotowania tego produktu, został przebadany na obecność HBsAg, przeciwciał HIV-1 i HIV- 2 oraz przeciwciał HCV przy użyciu licencjonowanych odczynników. Materiały pochodzenia ludzkiego reagujące na markery wirusowego zapalenia wątroby i przeciwciała przeciwko retrowirusom użyte do wytworzenia tego produktu, zostały poddane obróbce w celu inaktywacji czynników zakaźnych. Jednak żadna znana metoda badawcza nie może zapewnić, że produkty pochodzące ze źródeł ludzkich nie przenoszą infekcji. Zaleca się, aby ten produkt i wszystkie inne pochodzenia ludzkiego były traktowane zgodnie z praktykami bezpieczeństwa biologicznego na poziomie 2, opisanymi w Podręczniku bezpieczeństwa biologicznego Światowej Organizacji Zdrowia lub w innych równoważnych wytycznych.

Tylko do *in vitro*

*** WAŻNA UWAGA:** Wyniki muszą nadejść do **RIQAS** przed 17:00 czasu GMT, **OSTATNIEGO DNIA DATY FINALNEJ**. Jeżeli **ZAŁECANA DATA WYKONANIA OZNACZENIA** sprawia, że czasu jest zbyt mało, sugerujemy wcześniejsze przeprowadzenie oznaczenia, aby zdążyć przed datą finalną. Wyniki przesłane z opóźnieniem (po dacie finalnej), będą opracowywane jako spóźnione.

中文

血清（艾滋病、肝炎）：RQ9151

产品包装与收件日期确认书

请确认您所收到的样本数量正确无误，并且样本外观与下述“产品特性”中的内容描述一致

请确认您收到的样品瓶未发生破损等异常情况，如有任何问题，请立即联系朗道代表处

请您在收到本包装后登陆www.riqas.net确认收件具体日期

特征

每个周期含 24 个样本，12 个样本为一个包装。其中包含了 12 瓶液体（12 × 1.8ml）并且瓶身标有样本号。

样本的配制/储存/稳定性

将质控恢复到室温。轻轻搅拌，确保样品均匀，不要摇晃瓶身。为避免蒸发，使用后应立即盖紧小瓶，并储存在+2 至+8℃。样品的处理方式应与患者样品相同。开封后，请在 2 天内对样品进行分析。

安全

生物源材料，按潜在的传染物质处理。 每个用于制备本品的人血清或血浆供体均已使用有认证的试剂检测是否存在 HBsAg、HIV-1 和 HIV-2 抗体以及 HCV 抗体。用于生产本品的对病毒性肝炎标志物有反应的人源材料和逆转录病毒的抗体已被处理以灭活传染源。然而，没有一个已知的检测方法能保证来自人源的产品一定不会传播感染。建议本品和所有人体标本按照世界卫生组织《实验室生物安全手册》中描述的生物安全 2 级或其他同等指南进行处理。

仅供体外使用

重要注意事项：结果必须在“最终期限”当天 17:00（格林威治时间）之前送达 RIQAS。如果推荐分析日期所给时间不够，建议提早分析样品以保证您能在规定期限内完成。将不接受在最终日期之后提交的结果。

TIẾNG VIỆT

CHƯƠNG TRÌNH NGOẠI KIỂM HIV-HEPATITIS: RQ9151

XÁC NHẬN VỀ NHỮNG ĐẶC TÍNH MẪU VÀ NGÀY NHẬN

Xin vui lòng xác nhận rằng bạn đã nhận đúng và đầy đủ số lượng mẫu, những mẫu đó được mô tả như phần “ĐẶC TÍNH” dưới đây. Xin vui lòng xác nhận không có lọ mẫu nào bị vỡ hoặc hư hỏng và thông báo ngay cho đại diện của hãng Randox tại địa phương của bạn nếu có sai lệch. Sau cùng, xin vui lòng đăng nhập vào www.riqas.net để xác nhận thời gian chính xác mà bạn đã nhận bộ mẫu này.

ĐẶC ĐIỂM:

24 mẫu phân tích mỗi chu kỳ ngoại kiểm được cung cấp 6 tháng một lần, mỗi lần 12 mẫu phân tích. Hộp chứa 12 lọ mẫu lỏng (12 x 1.8 ml). Mỗi lọ được đánh số theo thứ tự phân tích mẫu.

CHUẨN BỊ/BẢO QUẢN/ĐỘ BỀN CỦA MẪU

Cho phép kiểm soát ở nhiệt độ phòng. Đảm bảo độ đồng nhất của mẫu bằng cách xoay vòng nhẹ, không được lắc lọ chứa mẫu.. Để tránh sự bay hơi, đóng nắp lọ ngay sau khi sử dụng và bảo quản ở +2 to +8°C. Mẫu nên được xử lý và phân tích giống như mẫu bệnh phẩm. Mẫu nên được phân tích trong vòng 2 ngày sau khi mở nắp.

ĐỘ AN TOÀN

Nguồn nguyên liệu sinh học. Xem như có khả năng lây nhiễm

Mỗi đơn vị hiến tặng huyết thanh hoặc huyết tương người được sử dụng để điều chế sản phẩm này đã được kiểm tra sự hiện diện của HBsAg, kháng thể với HIV-1 và HIV-2 và kháng thể với HCV bằng các thuốc thử được cấp phép. Nguyên liệu nguồn gốc từ người phản ứng với các dấu hiệu virus viêm gan và kháng thể đối với retrovirus được sử dụng để sản xuất sản phẩm này đã được xử lý để bất hoạt các tác nhân lây nhiễm. Tuy nhiên, không có phương pháp kiểm tra nào được biết đến có thể đảm bảo rằng các sản phẩm có nguồn gốc từ con người sẽ không lây nhiễm bệnh. Sản phẩm này và tất cả các mẫu bệnh phẩm của con người được khuyến nghị nên được xử lý theo các thực hành An toàn Sinh học Cấp độ 2 như được mô tả trong Hướng dẫn An toàn Sinh học trong Phòng thí nghiệm của Tổ chức Y tế Thế giới, hoặc các hướng dẫn tương đương khác. Chỉ sử dụng cho phân tích trong ống nghiệm.

LƯU Ý QUAN TRỌNG:

Kết quả phân tích phải được gửi đến cho RIQAS trước 17:00 GMT ngày hạn chót gửi trả kết quả. Phòng xét nghiệm nên phân tích mẫu sớm trước ngày khuyến cáo phân tích mẫu nếu cần để đảm bảo thời gian gửi trả kết quả. Kết quả phân tích trễ sẽ không được chấp nhận sau hạn chót gửi trả kết quả của mẫu tiếp theo.

TÜRKÇE

SEROLOJİ (HIV/HEPATİTİS): RQ9151

KİT ÖZELLİKLERİNİN VE ULAŞMA TARİHİNİN DOĞRULANMASI

Lütfen doğru sayıda örneğin bulunduğunu ve örneklerin görünüşlerinin aşağıda ÖZELLİKLER bölümünde belirtildiği gibi olduğunu doğrulayınız. Lütfen şişelerden hiç birinin kırık olmadığını doğrulayınız ve eğer herhangi bir uygunsuzluk varsa derhal yerel RANDOX sorumlunuzu uyarınız. Son olarak, lütfen www.riqas.net 'e giriş yaparak bu kiti hatasız teslim aldığınız tarihi doğrulayınız.

ÖZELLİKLER

Döngü başına 24 numune verilir ve 12'li paketlerde gönderilir. Paket 12 flakon likit malzeme (12 x 1.8 ml) içerir. Şişeler, örnek numaraları ile etiketlenmiştir.

NUMUNE HAZIRLAMA / DEPOLAMA / NUMUNELERİN STABİLİTESİ

Kontrolün oda sıcaklığına gelmesine izin verin. Numunelerin hafifçe döndürülerek homojen olduğundan emin olun, şişeleri sallamayın. Buharlaşmayı önlemek için, kullandıktan hemen sonra şişeyi kapatın ve +2 ila + 8°C'de saklayın. Örneklerle, hasta örnekleri ile aynı şekilde muamele edilmelidir. Bir kez açıldıktan sonra, lütfen örnekleri 2 gün içerisinde çalışınız.

GÜVENLİK

Biyolojik kaynak materyal. Potansiyel bulaşıcı gibi davranın.

Bu ürünün hazırlanmasında kullanılan her insan serumu veya plazma donör ünitesi, lisanslı reaktifler kullanılarak HBsAg, HIV-1 ve HIV-2 antikorları ve HCV antikorlarının varlığı açısından test edilmiştir. Viral hepatit belirteçleri için reaktif insan kaynaklı malzemeler ve bu ürünü üretmek için kullanılan retrovirüslere karşı antikorlar, bulaşıcı ajanları inaktive etmek için işlenmiştir. Bununla birlikte, bilinen hiçbir test yöntemi, insan kaynaklarından elde edilen ürünlerin enfeksiyon bulaştırmayacağını garanti edemez. Bu ürün ve tüm insan örneklerinin Dünya Sağlık Örgütü Laboratuvarı Biyogüvenlik Kılavuzu'nda veya diğer eşdeğer kılavuzlarda açıklanan Biyogüvenlik Seviye 2 uygulamalarına uygun olarak kullanılması önerilir.

Sadece **IN VITRO** kullanım içindir.

* **ÖNEMLİ NOT:** Sonuçlar, RIQAS'a **SON SONUÇ GÖNDERİM TARİHİ**'nde saat **17:00'de** ulaşmış olmalıdır. Eğer **ÖNERİLEN ANALİZ TARİHİ** sizin için uygun değilse, sonuç gönderim tarihine yetişmesi için için örneği daha erken analiz etmenizi öneririz. Geç sonuçlar, bir sonraki örneğin son sonuç gönderim tarihi sonrasında kabul edilmeyecektir.

POTVRDENIE CHARAKTERISTIKY KITU A DÁTUMU DORUČENIA

Prosím potvrdte doručenie správneho čísla vzorky a potvrdte, či vzhľad vzoriek zodpovedá charakteristike opísanej v sekcii nižšie. Prosím potvrdte, že žiadne fľaštičky nie sú rozbité, v opačnom prípade okamžite kontaktuje svojho obchodného zástupcu. Po prihlásení na www.rigas.net potvrdte a zadajte presný dátum, kedy Vám bol kit doručený.

CHARAKTERISTIKA

Cyklos obsahuje 24 vzoriek, ktoré sú odosielané v dvoch častiach balení po 12. Jedno balenie obsahuje 12 fľaštičiek kvapalného materiálu (12 x 1.8 ml). Fľaštičky sú označené číslom vzorky.

PRÍPRAVA/SKLADOVANIE/STABILITA VZORIEK

Nechajte kontrolu dosiahnuť izbovú teplotu. Jemným vírením sa uistíte, že vzorky sú homogénne, netraste fľaštičkami. Vyhnite sa vyparovaniu okamžitým zavorením fľaštičky po použití a skladujte pri teplote +2 až +8°C. Zaobchádzajte so vzorkami rovnakým spôsobom ako s patientskými vzorkami. Po otvorení analyzujte vzorky do 2 dní.

BEZPEČNOSŤ

Biologický zdrojový materiál. Považovať za potenciálne infekčné.

Každý jednotlivý darca ľudského séra alebo plazmy použitý pri príprave tohto produktu bol testovaný na prítomnosť HBsAg, protilátok proti HIV-1 a HIV-2 a protilátok proti HCV pomocou licencovaných reagensov. Materiály z ľudských zdrojov reaktívne na markery vírusovej hepatitídy a protilátky proti retrovírusom použitým na výrobu tohto produktu boli ošetrené na inaktiváciu infekčných agensov. Žiadna známa testovacia metóda však nemôže zaručiť, že výrobky pochádzajúce z ľudských zdrojov neprenášajú infekciu. Odporúča sa, aby sa s týmto produktom a so všetkými ľudskými vzorkami manipulovalo v súlade s postupmi biologickej bezpečnosti úrovne 2, ako sú opísané v príručke laboratórnej biologickej bezpečnosti Svetovej zdravotníckej organizácie WHO alebo v iných rovnocenných pokynoch. Iba na **IN VITRO** použitie.

* **POZNÁMKA:** Výsledky musia byť odoslané do **RIQAS** do **17:00 Hod GMT** vo **FINÁLNY DÁTUM**. Ak **ODPORÚČANÝ DÁTUM ANALÝZY** neposkytuje dostatočný čas, odporúčame analýzu vzorky skôr, aby sa zabezpečilo dodržanie termínu. Výsledky prijaté po finálnom termíne nebudú akceptované

Sep 2023



RANDOX QUALITY CONTROL CERTIFICATE OF ANALYSIS

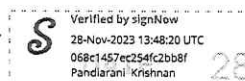
The Quality Control Department at Randox Laboratories Limited certifies that this product has been tested and meets all performance specifications and release requirements.

DATE OF MANUFACTURE:	2023-11
PRODUCT DESCRIPTION:	RIQAS SEROLOGY (HIV/HEPATITIS) PROGRAMME
CATALOGUE NUMBER:	RQ9151
CYCLE NUMBER:	12B
EXPIRY DATE:	2025-09

THIS KIT HAS PASSED QC FUNCTIONAL TESTING

APPROVED BY:

Pandiarani Krishnan



28-NOV-2023

QUALITY CONTROL REPRESENTATIVE

Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
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Directors: Dr S P FitzGerald CBE FREng DL BSc PhD DSc (Hons) FRAE Man. R P Kelly BSc FCA.

Randox Laboratories Ltd is a subsidiary of Randox Holdings Limited a company registered within Northern Ireland with company number N.J. 614690. VAT Registered Number: GB 151 6

RQ9151
Rev 2

9770-QC
Revision (5)
Last Date Printed: 27/11/2023



RQ9159
IMMUNOSUPPRESSANT PROGRAMME
PROGRAMME IMUNOSSUPRESSEUR
PROGRAMA IMUNOSSUPRESORES
PROGRAMA DE INMUNOSUPRESORES
PROGRAMMA IMMUNOSOPPRESSORI
PROGRAM LEKI IMMUNOSUPRESYJNE
CHƯƠNG TRÌNH NGOẠI KIỂM ỨC CHẾ MIỄN DỊCH
โปรแกรม IMMUNOSUPPRESSANT
免疫抑制剂计划
İMMÜNOSUPRESANLAR PROGRAMI

ENGLISH

IMMUNOSUPPRESSANT PROGRAMME: RQ9159

CONFIRMATION OF KIT CHARACTERISTICS AND RECEIPT DATE

Please confirm that the correct number of samples are present and that your samples have the appearance as indicated in the CHARACTERISTICS section below. Please confirm that none of the vials are broken and notify your local Randox representative immediately if there are any discrepancies. Finally, please log on to www.riqas.net to confirm the exact date on which you received this kit.

CHARACTERISTICS

The pack contains 6 vials of lyophilised material (6 x 2 ml). The vials are labelled with the sample number.

PREPARATION/STORAGE/STABILITY OF SAMPLES

The samples are sealed under vacuum. Open the vial very carefully, avoiding any loss of material and using a calibrated pipette reconstitute with an accurately measured 2 ml volume of freshly double distilled water at **+20°C to +25°C**. Replace the rubber stopper and ensure that samples are dissolved completely by swirling gently (ideally place on a roller for half an hour prior to analysis). Do not shake the vials. We recommend that the samples are run immediately following full reconstitution. The samples should be treated in the same way as patient samples.

SAFETY

Warning: Potentially Biohazardous Material

Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

For IN VITRO use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

*** IMPORTANT NOTE:** Results must arrive at **RIQAS** by **17:00 hrs GMT** on the **FINAL DATE**. If the **RECOMMENDED ANALYSIS DATE** gives insufficient time, we suggest that the sample is analysed earlier to ensure you meet the deadline. Late results will not be accepted after the final date for the next sample.

IMMUNOSUPPRESSANT PROGRAMME/ PROGRAMME IMUNOSSUPRESSEUR / PROGRAMA IMUNOSSUPRESORES /
PROGRAMA DE INMUNOSUPRESORES / PROGRAMMA IMMUNOSOPPRESSORI / PROGRAM LEKI IMMUNOSUPRESYJNE
โปรแกรม IMMUNOSUPPRESSANT / CHƯƠNG TRÌNH NGOẠI KIỂM ỨC CHẾ MIỄN DỊCH / 免疫抑制剂计划 / İMMÜNOSUPRESANLAR PROGRAMI

RETURN OF RESULTS / RETOUR DES RESULTATS / INVIO DEI RISULTATI / ENVIO DE RESULTADOS / RETORNO DOS RESULTADOS/
PRZESYLANIE WYNIKÓW / 回复结果 / GỬI TRẢ KẾT QUẢ / SONUÇ GÖNDERİM TARİHLERİ / ODOŚLANIE WYŚLEDKÓV

CYCLE 9A / CICLO 9A / CYKL 9A / 返回结果周期 9A / CHU KỲ 9A / DÖNEM 9A / CYKLUS 9A

SAMPLE NO / ECHANTILLON NO. / N. CAMPIONE / N° DE MUESTRA / AMOSTRA Nº. / NR PRÓBK / 样品号 / ตัวอย่างตรวจที่ / MĀU SÓ / ÖRNEK NO / Č. VZORKY	RECOMMENDED ANALYSIS DATE/ DATE RECOMMANDE POUR L' ANALYSE/ DATA DI ANALISI RACCOMANDATA/ FECHA DE ANALISIS RECOMENDADA/ ZALECANA DATA WYKONANIA OZNACZENIA/ 推荐分析日期 / วันที่แนะนำให้ทำการวิเคราะห์ / NGÀY KHUYẾN CÁO PHÂN TÍCH / ÖNERİLEN ÇALIŞMA TARİHİ / ODPORÚČANÝ DÁTUM ANALÝZY	* FINAL DATE/ *DATE LIMITE/ * DATA FINALE/ *FECHA FINAL/ * DATA KOŃCOWA/ *最终日期 * วันสุดท้ายของการส่งผลกลับ / * HẠN CUỐI GỬI TRẢ KẾT QUẢ * SON SONUÇ GÖNDERİM TARİHİ / *FINALNY TERMÍN
1	11.03.24	18.03.24
2	15.04.24	22.04.24
3	13.05.24	20.05.24
4	10.06.24	17.06.24
5	15.07.24	22.07.24
6	12.08.24	19.08.24

FRANÇAIS

PROGRAMME IMUNOSSUPRESSEUR: RQ9159

CONFIRMATION DES CARACTERISTIQUES DU KIT ET DE LA DATE DE RECEPTION:

Veuillez vérifier que l'ensemble des échantillons soient présents dans le coffret et que leur apparence est conforme comme indiqué dans la section ci-dessous. De plus assurez-vous qu'aucun des flacons ne soient brisés et en informer immédiatement votre représentant Randox si cela est le cas. Enfin, il est nécessaire de se connecter à www.riqas.net pour confirmer la date exacte à laquelle vous avez reçu ce kit.

CARACTERISTIQUE

Le coffret est composé de 6 flacons de matériel lyophilisé (6 x 2 ml). Le numéro de l'échantillon est indiqué sur l'étiquette du flacon.

PREPARATION/STOCKAGE/STABILITE DES ECHANTILLONS

Les échantillons sont scellés sous vide. Ouvrir le flacon avec précaution, pour éviter la perte de matériel. Utiliser une pipette étalonnée, et mesurer 2 ml avec précision d'eau bidistillée entre +20 et +25°C. Remplacer le bouchon en caoutchouc et s'assurer que les échantillons sont dissous complètement en procédant par retournements successifs (idéalement, placer sur un rouleau pendant une demi-heure avant l'analyse). Ne pas secouer les flacons. Nous vous recommandons d'analyser les échantillons immédiatement après le temps de reconstitution. Les échantillons doivent être traités comme vos échantillons patients.

SÉCURITÉ

Produit à risque biologique

Ce matériel d'origine humaine, dont les donneurs ont été testés pour la présence d'anticorps de "l'Human Immunodeficiency Virus" (HIV 1, HIV 2), l'antigène de surface de l'Hépatite B (HbsAg), et d'anticorps du virus de l'Hépatite C (HCV) et ont été trouvés négatifs. Ces tests ont été effectués par des méthodes approuvées par la FDA (US Food and Drug Administration). Cependant, aucun test ne pouvant apporter une garantie totale sur le caractère non infectieux de ce produit.

Réservé uniquement pour un usage **IN VITRO**. Ne pas pipeter à la bouche. Respecter les précautions d'usage pour la manipulation des réactifs de laboratoire.

*** NOTE IMPORTANTE:** Les résultats **RIQAS** doivent parvenir au Département **RIQAS** au plus tard le lundi midi selon la **DATE FINALE**. Nous vous recommandons d'analyser les échantillons quelques jours avant cette date finale. Les résultats en retard ne seront pas acceptés après la date finale de l'échantillon suivant. Vous pouvez envoyer vos résultats via Riqasnet ou par e.mail à l'adresse suivante: mail@riqas.com.

PORTUGUÊS

PROGRAMA IMUNOSSUPRESORES: RQ9159

CONFIRMAÇÃO DAS CARACTERÍSTICAS DO KIT E DATA DE RECEPÇÃO

Agradecemos-lhe que confirme que recebeu o número correcto de amostras e que estas têm o aspecto descrito na secção CARACTERÍSTICAS deste documento. Verifique também, se nenhum dos frascos está partido e notifique o seu representante local da Randox caso encontre alguma discrepância. Finalmente, acesse ao www.riqas.net para confirmar a data exacta em que recebeu este kit.

CARACTERÍSTICAS

O Kit contém 6 frascos com material liofilizado (6 x 2 ml). Os frascos estão rotulados com o número da amostra.

PREPARAÇÃO/CONSERVAÇÃO/ESTABILIDADE DAS AMOSTRAS

As amostras encontram-se fechadas em vácuo. Abra o frasco cuidadosamente, evitando perdas de material e, usando uma **pipeta calibrada**, reconstitua com a **exactamente** 2 ml de água recentemente destilada a **+20°C- +25°C**. Reponha a rolha de borracha e dissolva completamente o material agitando suavemente (pode colocar os frascos no agitador durante 30 minutos antes da análise). Recomendamos que faça os testes imediatamente após a reconstituição. As amostras devem ser tratadas da mesma forma que as amostras dos doentes.

SEGURANÇA

Aviso: material com potencial risco biológico

O material de origem humana usado, foi testado ao nível do dador para os vírus HIV 1 e HIV 2, assim como para HbsAg e HCV. Os métodos usados para efectuar estes testes têm a aprovação do FDA, contudo e uma vez que nenhum método pode garantir totalmente a ausência de agentes infecciosos, este material deve ser tratado como potencialmente perigoso e eliminado respeitando as boas práticas laboratoriais.

Apenas para **IN VITRO**. Não pipete com a boca e respeite as Boas Práticas Laboratoriais para o manuseamento de material potencialmente contaminado.

*** NOTA IMPORTANTE:** Os resultados têm de chegar ao **RIQAS** até às **17:00 hr GMT** na **DATA FINAL**. Se a **DATA RECOMENDADA PARA ANÁLISE** não der tempo suficiente, sugerimos que a amostra seja analisada mais cedo para garantir o cumprimento da data limite. Resultados atrasados não serão aceites depois a data final da amostra seguinte.

PROGRAMA DE INMUNOSUPPRESORES: RQ9159**CONFIRMACION DE LAS CARACTERISTICAS DEL KIT Y LA FECHA DE RECEPCION.**

Por favor, Asegúrese de que ha recibido el numero correcto de muestras y que estas cumplen con la presentación indicada en la sección "CARACTERISTICAS" que encontrara a continuación. Por favor, confirme que ninguna de las muestras ha resultado dañada y contacte a su Representante local de Randox inmediatamente en el caso de que hubiese alguna discrepancia. Por ultimo, Acceda a www.riqas.net para confirmar la fecha exacta en la que recibió el kit.

CARACTERÍSTICAS

El paquete contiene 6 frascos de muestras liofilizadas (6 x 2 ml). Los frascos están marcados con el número de la muestra.

PREPARACIÓN/ ALMACENAMIENTO/ ESTABILIDAD DE LAS MUESTRAS

Las muestras están cerradas al vacío. Abrir el frasco con mucho cuidado, para evitar cualquier pérdida de material y reconstituir con exactamente 2 ml de agua destilada obtenida recientemente y conservada entre +20°C y +25°C. Volver a colocar el tapón de goma para cerrar el frasco y asegurarse de que los componentes liofilizados estén completamente disueltos girando el frasco suavemente (idealmente debe ponerlos en una maquina girador durante media hora antes de analizar). No agitar los frascos. Recomendamos que se analice las muestras inmediatamente después de reconstitución. Debe manejar las muestras en la misma manera que las muestras de pacientes.

SEGURIDAD**Advertencia: Material Potencialmente Biopeligroso**

El material de base humana de donde vienen estas muestras ha sido analizado, siendo negativo para anticuerpos HIV 1, HIV 2, HbsAg y HCV. Hemos usado métodos aprobados por la FDA para realizar estas pruebas. Sin embargo, ya que ningún método pueda ofrecer una seguridad completa en cuanto a la ausencia de agentes infecciosos, se debe manejar este material y las muestras de pacientes como si fueran capaces de transmitir enfermedades infecciosas y debe tirarlos de manera apropiada.

Sólo para IN VITRO. No pipetear con la boca. Debe seguir las precauciones normales para el manejo de reactivos de laboratorio.

*** NOTA IMPORTANTE:** Los resultados deben arribar a **RIQAS** a las **17:00 horas GMT** en la **FECHA FINAL**. Si la **FECHA RECOMENDADA PARA ANALISIS** dada es insuficiente, le sugerimos que analice la muestra antes para asegurarse que la tenga lista en la fecha final. Los resultados tardíos nos serán aceptados después de la fecha final de la siguiente muestra.

ITALIANO**PROGRAMMA IMMUNOSUPPRESSORI: RQ9159****CONFERMA DELLE CARATTERISTICHE DEL KIT E DELLA DATA DI RICEZIONE**

Si prega di confermare che sia presente il numero corretto di campioni e che i vostri campioni siano come indicato nella sezione CARATTERISTICHE qui sotto. Confermare che nessuna fiala sia rotta ed informare immediatamente il rappresentante Randox locale se ci fossero delle discrepanze. Infine, si prega di accedere al sito www.riqas.net per confermare la data esatta in cui si è ricevuto questo kit.

CARATTERISTICHE

Il pacco contiene 6 fiale di materiale liofilo (6 x 2 ml). Le fiale sono etichettate con il numero del campione.

PREPARAZIONE/CONSERVAZIONE/ STABILITA' DEI CAMPIONI

I campioni sono chiusi sottovuoto. Aprire la fiala con estrema cautela, evitando qualsiasi perdita di materiale e usando una pipetta calibrata ricostituire con un volume accuratamente misurato di 2 ml di acqua appena bidistillata a **+20°C to +25°C**. Rimettere il tappo di gomma e assicurarsi che i campioni siano dissolti completamente agitando delicatamente (l'ideale sarebbe utilizzare un agitatore per mezz'ora prima dell'analisi). Raccomandiamo di dosare i campioni immediatamente dopo la ricostituzione. I campioni devono essere trattati nello stesso modo in cui vengono trattati i campioni di pazienti.

SICUREZZA**Attenzione: materiale potenzialmente pericoloso**

Il materiale di origine umana da cui è derivato questo prodotto è stato testato sui donatori, e ha dato **ESITO NEGATIVO**, per l'anticorpo del virus da Immunodeficienza Umana (HIV 1, HIV 2), per l'Antigene di Superficie del virus dell'Epatite B (HbsAg), e per l'anticorpo del virus dell'Epatite C (HCV). Per questi test sono stati usati metodi approvati dall'FDA.

Poiché nessun metodo di indagine può dare assoluta garanzia di assenza di questi agenti infettivi, si raccomanda di trattare e smaltire il prodotto e tutti i campioni dei pazienti con cautela.

Solo per uso **IN VITRO**. Non utilizzare pipette a bocca. Utilizzare le normali precauzioni necessarie per la manipolazione di reagenti di laboratorio.

*** NOTA IMPORTANTE:** I risultati devono arrivare a **RIQAS** entro le **17:00 GMT** dell' **ULTIMA DATA**. Se la **DATA RACCOMANDATA PER L'ANALISI** non fornisce tempo a sufficienza, suggeriamo di analizzare il campione prima per essere certi di rispettare la scadenza. Risultati in ritardo non saranno accettati dopo l'ultima data del campione successivo.

POLSKI

PROGRAM LEKI IMMUNOSUPRESYJNE: RQ 9159

POTWIERDZENIE CHARAKTERYSTYKI ZESTAWU I DATY ODBIORU

Prosimy o potwierdzenie, że zestaw zawiera odpowiednią ilość próbek i Państwa próbki wyglądają tak, jak w podanej poniżej CHARAKTERYSTYCE. Prosimy o potwierdzenie, że żadna z próbek nie jest zbita, a jeśli są jakiegokolwiek niezgodności prosimy o niezwłoczne zgłoszenie tego lokalnemu przedstawicielowi.

Następnie prosimy o zalogowanie się na www.riqas.net w celu potwierdzenia dokładnej daty otrzymania zestawu.

CHARAKTERYSTYKA

Opakowanie zawiera 6 fiolek próbek liofilizowanych (6 x 2 ml). Fiolki są oznakowane numerem próbek.

PRZYGOTOWANIE/PRZECHOWYWANIE/STABILNOŚĆ PRÓBEK

Próbki są zamknięte metodą próżniową. Otworzyć fiolkę bardzo ostrożnie, unikając utraty materiału i rekonstruować w dokładnie odmierzonej objętości 2 ml świeżo podwójnie destylowanej wodzie w temperaturze od +20 do +25°C. Umieścić gumowy korek i upewnić się, czy próbka uległa rozpuszczeniu poprzez delikatne rolowanie (najlepiej umieścić próbkę na mieszadle na pół godziny przed oznaczeniem). Proszę nie wstrząsać fiolką. Wskazane jest wykonanie oznaczenia natychmiast po wykonaniu powyższej rekonstrukcji.

Zaleca się aby postępować z próbką tak samo jak z materiałami pobranymi od pacjentów.

BEZPIECZEŃSTWO

Ostrożnie: Materiał potencjalnie szkodliwy biologicznie.

Próbki zawierają krew ludzką. Każdy dawca został przebadany na obecność przeciwciał wirusów HIV1 i HIV2 oraz antygenu powierzchniowego zapalenia wątroby typu B (Hbs Ag) i typu C (HCV). Próbki dały wynik negatywny. Przeprowadzone badania są potwierdzone przez FDA. Jednakże, żadna metoda nie daje całkowitej pewności nieobecności czynników zakaźnych, dlatego ten materiał i wszystkie próbki pobrane od pacjentów powinny być traktowane jako potencjalne źródło chorób zakaźnych.

Tylko do *in vitro*. Nie należy pipetować ustami. Zachować ostrożność wymaganą przy używaniu odczynników laboratoryjnych.

***UWAGA:** Wyniki muszą dotrzeć do RIQAS do godziny 17:00 czasu GMT w dniu DATY FINALNEJ. Termin ten dotyczy użytkowników programu RIQASnet. Jeżeli ZALECANA DATA OZNACZENIA jest zbyt późna, sugeruje się przeprowadzenie wcześniejszej analizy, aby uzyskać czas na przesłanie wyników. Spóźnione wyniki przesłane po dacie finalnej następnej próbki nie zostaną przyjęte.

ภาษาไทย

โปรแกรม IMMUNOSUPPRESSANT: RQ9159

ยืนยันคุณลักษณะชุด kit และวันที่ได้รับชุด kit

โปรดยืนยันว่าจำนวนของตัวอย่างถูกต้อง เป็นตัวอย่างในปัจจุบันและตัวอย่างของท่านมีลักษณะตามที่ระบุไว้ในคุณลักษณะด้านล่าง

โปรดยืนยันว่าไม่มีขวดแตกและให้แจ้งตัวแทนจำหน่ายของท่านทันทีหากมีความผิดปกติใดๆ โปรดเข้าสู่ระบบ www.riqas.net เพื่อยืนยันวันที่ท่านได้รับชุดkit

คุณลักษณะ

ใน 1 กล่อง ประกอบด้วยตัวอย่างที่เป็นผงแห้งบรรจุในขวดขนาด 2 มิลลิลิตร จำนวน 6 ขวด (6 x 2 ml.) โดยแต่ละขวดจะมีหมายเลขตัวอย่างระบุไว้ที่ข้างขวด

การเตรียมตัวอย่างตรวจ / การเก็บรักษา / ความเสถียรของตัวอย่าง

ตัวอย่างปิดผนึกภายใต้สุญญากาศ เปิดแต่ละขวดอย่างระมัดระวัง หลีกเลี่ยงการสูญเสียของตัวอย่าง และใช้ไปตเปิดที่เคลือบแล้ว ละลายตัวอย่างด้วย freshly double distilled water 2 มิลลิลิตร ที่อุณหภูมิ 20-25 °C ปิดขวดอย่างถูกต้องและให้แน่ใจว่าตัวอย่างมีการละลายอย่างสมบูรณ์โดยการหมุนขวดเป็นวงกลมอย่างช้าๆ (swirling) (วางอยู่บน roller ครั้งชั่วโมงก่อนทำการวิเคราะห์) ห้ามเขย่าขวด เมื่อละลายอย่างสมบูรณ์แล้วให้ทำการวิเคราะห์ตัวอย่างทันที ควรทำการตรวจวิเคราะห์เช่นเดียวกับการตรวจตัวอย่างผู้ป่วย

ความปลอดภัย

ข้อควรระวัง : Potentially Biohazardous Material

ตัวอย่างตรวจได้มาจาก human source ของผู้บริจาคโลหิต ซึ่งได้ทำการตรวจว่ามีความปลอดภัยจากแอนติบอดีของไวรัส HIV (HIV1, HIV2) HBs Ag และ HCV Antibody โดยมีผลการตรวจเป็น Non-Reactive และได้ใช้วิธีการที่ได้รับการพิสูจน์จาก FDA ในการตรวจวัด test ต่างๆ อย่างไรก็ตามไม่มีวิธีการใด ที่จะสามารถให้ความมั่นใจได้ว่าจะปลอดภัยจาก infectious agents

ดังนั้นควรระวังทำการตรวจวิเคราะห์ตัวอย่าง และ ตัวอย่างจาก ผู้ป่วยด้วยความระมัดระวัง

สำหรับ IN VITRO เท่านั้น อย่าเปิดทางปาก ข้อควรระวังให้ปฏิบัติตาม normal precautions สำหรับน้ำยาวิเคราะห์

หมายเหตุ สำคัญ ผลจะต้องถึง RIQAS ในเวลา 17.00 hrs. GMT ของวันสุดท้ายของการส่งผลกลับ (Final Date) ขอแนะนำให้ทำการวิเคราะห์ตัวอย่าง ก่อนจะถึงวันสุดท้ายของการส่งผลกลับ (Final Date) LATE RESULTS หรือการส่งผลช้า จะไม่ได้รับการประเมิน ถ้าส่งผลหลังจาก Final Date ของ sample ถัดไป

CHƯƠNG TRÌNH NGOẠI KIỂM ÚC CHẾ MIỄN DỊCH: RQ9159

XÁC NHẬN VỀ ĐẶC ĐIỂM CỦA BỘ KIT VÀ NGÀY NHẬN MẪU

Xin hãy xác nhận đúng số lượng mẫu và bề mặt ngoài của mẫu giống như đặc điểm nêu phía dưới. Hãy xác nhận không có mẫu nào bị vỡ và thông báo cho đại diện phân phối ngay lập tức nếu xuất hiện dấu hiệu khác thường của mẫu. Cuối cùng, hãy đăng nhập vào www.riqas.net để xác nhận ngày bạn nhận được mẫu.

ĐẶC ĐIỂM

Mỗi hộp bao gồm 6 lọ dạng đông khô, mỗi lọ 2ml và được dán nhãn số theo thứ phân tích.

CHUẨN BỊ/BẢO QUẢN/ĐỘ BỀN CỦA MẪU

Lọ mẫu được đóng nắp chân không. Mở nắp lọ cẩn thận tránh làm thất thoát, pha loãng với chính xác 2ml nước cất hai lần ở $+20^{\circ}\text{C} - +25^{\circ}\text{C}$. Đậy nút cao su và đảm bảo rằng mẫu được hòa tan hoàn toàn bằng cách xoay nhẹ nhàng (tốt nhất là để trên máy lắc trộn trong 30 phút trước khi phân tích). Chú ý không được lắc mạnh. Chúng tôi khuyến cáo mẫu nên được phân tích ngay sau khi thực hiện đầy đủ các bước hoàn nguyên. Mẫu được xử lý và phân tích giống mẫu bệnh nhân.

ĐỘ AN TOÀN

Cảnh báo: Khả năng có độc tính sinh học với nguồn vật liệu

Mẫu có nguồn gốc từ người và đều được kiểm tra không có phản ứng với kháng thể HIV (HIV 1 & HIV 2), HbsAg, HCV. Phương pháp kiểm tra được chấp nhận bởi tổ chức FDA. Tuy nhiên không có phương pháp kiểm tra nào có thể đảm bảo tuyệt đối sự âm tính của tác nhân truyền nhiễm. Đề bảo đảm an toàn tuyệt đối, mẫu này và toàn bộ mẫu bệnh nhân phải được thao tác xử lý giống như mẫu truyền nhiễm.

Chỉ dùng cho phân tích trong ống nghiệm. Không được hút mẫu bằng miệng. Tuân thủ các khuyến cáo thông thường yêu cầu trong quy trình xử lý hoá chất phòng xét nghiệm.

LƯU Ý QUAN TRỌNG:

Kết quả phân tích phải được gửi đến cho RIQAS trước 17:00 GMT ngày hạn chót gửi trả kết quả. Phòng xét nghiệm nên phân tích mẫu sớm trước ngày khuyến cáo phân tích mẫu nếu cần để đảm bảo thời gian gửi trả kết quả. Kết quả phân tích trễ sẽ không được chấp nhận sau hạn chót gửi trả kết quả của mẫu tiếp theo.

中文

免疫抑制剂计划: RQ9159

确认试剂盒特性和接收日期

请确认样品的数量正确及外观如下面特性描述一致。请确认没有小瓶破损，如果有任何差异请立即通知当地的朗道的代表。最后，请登录 www.riqas.net 确认您用来接收该试剂盒的确切日期

特性

此试剂盒包含 6 瓶冻干材料（6×2 毫升）。每瓶上标注了样本编号。

样本的配制/储存/稳定性

样本是在真空密封状态。小心打开每个小瓶，避免损失任何材料，在 $+20^{\circ}\text{C} \sim +25^{\circ}\text{C}$ 环境下使用经校准的移液器准确测量的 2ml 新鲜蒸馏水来复溶每瓶样本。除去橡胶塞，并确保样本通过涡旋轻轻完全溶解（理想状态下在分析前放在滚筒上半小时）。不要摇晃瓶子。我们建议完全复溶后立即检测样本。样本处理应与患者标本相同。样本不使用时，

安全

警告：具有潜在生物安全危险的材料

这款产品中所使用的有献血者获得的人源物质已经进行了人类免疫缺陷病毒（HIV1，HIV2）抗体、乙肝表面抗原（HBsAg）和丙型肝炎病毒（HCV）抗体检测，结果为阴性。这些试验使用的是 FDA 批准的方法。然而，由于感染性病原体的缺失，没有方法能够完全保证安全，所以这种物质和所有患者标本应如同传染病传播的处理和做出相应的处置。

用于体外诊断。不要用嘴吸允。练习进行处理，需要实验室试剂的常规注意事项。

***重要提示：**结果必须在最后期限 **17:00GMT** 反馈给 **RIQAS**。如果推荐分析日期给出的时间不足，我们建议提早进行样品分析，以确保您复合最后期限。晚于截止日期的结果将不被接受。

TÜRKÇE

İMMÜNOSUPRESANLAR PROGRAMI: RQ9159

KİT ÖZELLİKLERİNİN VE ULAŞMA TARİHİNİN DOĞRULANMASI

Lütfen doğru sayıda örneğin bulunduğunu ve örneklerin görünüşlerinin aşağıda ÖZELLİKLER bölümünde belirtildiği gibi olduğunu doğrulayınız. Lütfen şişelerden hiç birinin kırık olmadığını doğrulayınız ve eğer herhangi bir uygunsuzluk varsa derhal yerel RANDOX sorumlunuzu uyarınız. Son olarak, lütfen www.riqas.net 'e giriş yaparak bu kiti hatasız teslim aldığınız tarihi doğrulayınız.

ÖZELLİKLER

Paket, 6 şişe liofilize materyali içerir (6 x 2 ml). Şişeler; örnek numaraları ile etiketlenmiştir.

NUMUNE HAZIRLAMA / DEPOLAMA / NUMUNELERİN STABİLİTESİ

Örnekler vakumlanarak ambalajlanmıştır. Şişeyi, herhangi bir materyal kaybı olmayacak şekilde dikkatlice açınız ve kalibre edilmiş bir pipetle tam 2 ml'lik hacimde taze distile su ile **+20°C -+25°C**'de sulandırınız. Plastik tıpayı yerleştiriniz ve hafifçe çevirerek örneklerin tam olarak çözünmesini sağlayınız. (İdeali analizden yarım saat önce bir karıştırıcı üzerine koymaktır). Çalkalayınız. Örnekler tam olarak çözününce hemen çalışmanız önerilmektedir. Örnekler, hasta örnekleri ile aynı şekilde muamele edilmelidir.

GÜVENLİK

Uyarı: Potansiyel olarak biyolojik tehlikeli madde

Bu ürünün elde edildiği insan kaynaklı materyal donör seviyesinde İnsan İmmünyetmezlik Virüsü (HIV 1, HIV 2) antikor, Hepatit B yüzey Antijeni (HbsAg), ve Hepatit C Virüs (HCV) antikor açısından test edilmiş ve NON-REAKTİF olarak bulunmuştur. Bu testler için FDA onaylı metotlar kullanılmıştır. Fakat yine de, hiç bir metot enfeksiyon ajanlarının yokluğu için tam garanti vermediğinden bu materyal ve tüm hasta örnekleri muhtemel enfeksiyon hastalığı taşıyıcısı varsayılarak çalışılmalı ve uygun şekilde atığa gönderilmelidir.

Sadece *IN VITRO* kullanım içindir. Ağızla pipetleme yapmayınız. Laboratuvar reaktiflerinin örneklenmesi için gerekli normal önlemleri uygulayınız.

* **ÖNEMLİ NOT:** Sonuçlar, RIQAS'a **SON SONUÇ GÖNDERİM TARİHİ**'nde saat **17:00**'de ulaşmış olmalıdır. Eğer **ÖNERİLEN ANALİZ TARİHİ** sizin için uygun değilse, sonuç gönderim tarihine yetişmesi için için örneği daha erken analiz etmenizi öneririz. Geç sonuçlar, bir sonraki örneğin son sonuç gönderim tarihi sonrasında kabul edilmeyecektir.

SLOVENSKY

IMMUNOSUPPRESSANT PROGRAMME: RQ9159

POTVRDENIE CHARAKTERISTIKY KITU A DÁTUMU DORUČENIA

Prosím potvrdte doručenie správneho čísla vzorky a potvrdte, či vzhľad vzoriek zodpovedá charakteristike opísanej v sekcii nižšie. Prosím potvrdte, že žiadne fľaštičky nie sú rozbité, v opačnom prípade okamžite kontaktujte svojho obchodného zástupcu. Po prihlásení na www.riqas.net potvrdte a zadajte presný dátum, kedy Vám bol kit doručený.

CHARAKTERISTIKA

Balenie obsahuje 6 fľaštičiek lyofilizovaných vzoriek (6 x 2 ml). Fľaštičky sú označené číslom vzorky.

PRÍPRAVA/SKLADOVANIE/STABILITA VZORIEK

Fľaštička je vákuovo uzatvorená. Otvorte fľaštičku veľmi opatrne, vyhnite sa stratám materiálu a použitím **nakalibrovanej pipety** rekonšitujte presne **2 ml** objemu čerstvo destilovanej vody pri teplote **+20°C to +25°C**. Zatvorte gumenou zátkou a jemným vírením sa uistite, že vzorky sú úplne rozpustené (ideálne umiestnite na miešadlo, roler, na pol hodinu pred samotnou analýzou). Netraste fľaštičkami. Odporúčame analýzu vzoriek okamžite po úplnej rekonštitúcii. So vzorkami zaobchádzajte rovnakým spôsobom ako s patientskými vzorkami.

BEZPEČNOSŤ

Upozornenie: Potenciálne biohazardný materiál

Tento materiál je vyrobený z ľudského zdroja a bol testovaný na úrovni darcu na Human Immunodeficiency Virus (HIV 1, HIV 2) protilátky, Hepatitídu B povrchový antigen (HbsAg), a protilátky Hepatitídy C (HCV) a bol preukázaný ako NEREAKTÍVNY. Boli použité metódy schválené federáciou FDA. Keďže žiadna metóda nezabezpečí úplnú dôveryhodnosť, zaobchádzajte s materiálom a všetkým vzorkami pacientov ako so vzorkami, ktoré sú schopné prenášať infekčné ochorenia.

Iba na *IN VITRO* použitie. Neipetujte ústami. Vykonať bežné opatrenia vyžadované pri manipulácii s laboratórnymi reagensiami.

* **POZNÁMKA:** **Výsledky musia byť odoslané do RIQAS do 17:00 Hod GMT vo FINÁLNY DÁTUM. Ak ODPORÚČANÝ DÁTUM ANALÝZY neposkytuje dostatočný čas, odporúčame analýzu vzorky skôr, aby sa zabezpečilo dodržanie termínu. Výsledky prijaté po finálnom termíne nebudú akceptované.**

Nov 2023



RANDOX QUALITY CONTROL CERTIFICATE OF ANALYSIS

The Quality Control Department at Randox Laboratories Limited certifies that this product has been tested and meets all performance specifications and release requirements.

DATE OF MANUFACTURE:	2023-07
PRODUCT DESCRIPTION:	RIQAS MONTHLY SPECIFIC PROTEINS PROGRAMME
CATALOGUE NUMBER:	RQ9187
CYCLE NUMBER:	4B
EXPIRY DATE:	2025-06

THIS KIT HAS PASSED QC FUNCTIONAL TESTING

APPROVED BY:

DATE:

24-JUL-23

QUALITY CONTROL REPRESENTATIVE

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Directors: Dr S P FitzGerald CBE FREng DL BSc PhD DSc (Hons) FIAE Man. R P Kelly BSc FCA.

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9770-QC

Revision (5)

Last Date Printed: 24/07/2023

RQ9187
Revision(1)

English

MONTHLY SPECIFIC PROTEINS PROGRAMME: RQ9187

CONFIRMATION OF KIT CHARACTERISTICS AND RECEIPT DATE

Please confirm that the correct number of samples are present and that your samples have the appearance as indicated in the CHARACTERISTICS section below. Please confirm that none of the vials are broken and notify your local Randox representative immediately if there are any discrepancies. Finally, please log on to www.riqas.net to confirm the exact date on which you received this kit.

CHARACTERISTICS

The pack contains 6 vials of liquid 1 ml samples. The vials are labelled with the sample number.

PREPARATION/STORAGE/STABILITY OF SAMPLES

The samples are ready for use. Allow the samples to come to room temperature before analysis. To avoid evaporation, replace the rubber stopper and close vial immediately after use and store at +2 to +8°C. Once opened please analyse the sample within 2 days. The samples should be treated in the same way as patient samples. The samples should be stored at 2 - 8°C when not in use.

SAFETY

The serum is human based. It has been source tested and found to be negative for HBsAg and antibodies to HIV. For complete protection however, it is recommended that the serum be handled as carefully as patient specimens.

For IN VITRO use only.

*** IMPORTANT NOTE:** Results must arrive at **RIQAS** by **17:00 HRS GMT** on the **FINAL DATE**. If the **RECOMMENDED ANALYSIS DATE** gives insufficient time, we suggest that the sample is analysed earlier to ensure you meet the deadline. Late results will not be accepted after the final date for the next sample.

MONTHLY SPECIFIC PROTEINS PROGRAMME/ PROGRAMME PROTEINES SPECIFIQUES MENSUEL / PROGRAMMA MENSILE PER PROTEINE SPECIFICHE /
 PROGRAMA MENSUAL DE PROTEÍNAS ESPECÍFICAS/ PROGRAMA MENSUAL DE PROTEÍNAS ESPECÍFICAS /
 MANED PROGRAM FOR SPECIFIKKE PROTEINER / MANADS PROGRAM SPECIFIKA PROTEINER/ ΜΗΝΙΑΙΟ ΠΡΟΓΡΑΜΜΑ ΕΙΔΙΚΩΝ ΠΡΩΤΕΪΝΩΝ
 MIESIĘCZNY PROGRAM OZNACZANIA BIAŁEK SPECJALNYCH / 每月特定蛋白质分析程序 /
 CHƯƠNG TRÌNH TRAO ĐỔI PROTEIN ĐẶC BIỆT HÀNG THÁNG / AYLIK SPESİFİK PROTEİNLER PROGRAMI

RETURN OF RESULTS / DATES de RETOUR / INVIO DEI RISULTATI / ENVIO DE RESULTADOS
 PLAN FOR INSENDELSE AF / CYKEL FÖR / ΚΥΚΛΟΣ ΕΠΙΣΤΡΟΦΗΣ / GỬI TRẢ KẾT QUẢ / SONUÇ GÖNDERİM TARİHLERİ/ ODOSLANIE VÝSLEDKOV

CYCLE 5A / CICLO 5A / RESULTATER 5A / RESULTATRETUR 5A /
 ΑΠΟΤΕΛΕΣΜΑΤΩΝ 5Α / CYKL ZWROTU WYNIKÓW 5A / 返回结果周期 5A / CHU KỲ 5A / DÖNEM 5A / CYKLUS 5A

SAMPLE NO / ECHANTILLON NO. /
 N. CAMPIONE / N° DE MUESTRA /
 AMOSTRA N° / PRØVENR. /
 ΑΡ. ΔΕΙΓΜΑΤΟΣ / PROV NR. /
 NR PRÓBK / 样品号 / MẪU SỐ /
 ŐRNEK NO / Ć.VZORKY

RECOMMENDED ANALYSIS DATE/ DATE RECOMMANDE POUR L' ANALYSE/
 DATA DI ANALISI RACCOMANDATA/ FECHA DE ANALISIS RECOMENDADA/
 DATA RECOMENDADA PARA ANÁLISE/ ANBEFALET ANALYSEDATO/
 REKOMMENDERAT ANALYSDATUM/ ΣΥΝΙΣΤΩΜΕΝΗ ΗΜΕΡΟΜΗΝΙΑ ΑΝΑΛΥΣΗΣ
 ZALECANA DATA WYKONANIA OZNACZENIA/ 推荐分析日期/NGÀY KHUYẾN CÁO PHÂN TÍCH/
 ÖNERİLEN ANALİZ TARİHİ / ODPORÚČANÝ DÁTUM ANALÝZY

* FINAL DATE/ *DATE LIMITE/ DATA FINALE /
 * FECHA FINAL/ DATA FINAL/ * SLUTDATO /
 * SLUTDATUM/ *ΤΕΛΙΚΗ ΗΜΕΡΟΜΗΝΙΑ /
 * DATA KOŃCOWA/ *最终日期
 * HẠN CUỐI GỬI TRẢ KẾT QUẢ
 * SON SONUÇ GÖNDERİM TARİHİ /
 * FINÁLNÝ TERMÍN

1	11.03.24	18.03.24
2	15.04.24	22.04.24
3	13.05.24	20.05.24
4	10.06.24	17.06.24
5	08.07.24	15.07.24
6	12.08.24	19.08.24

PROGRAMME PROTEINES SPECIFIQUES MENSUEL: RQ9187

CONFIRMATION DES CARACTERISTIQUES DU KIT ET DE LA DATE DE RECEPTION :

Veuillez vérifier que l'ensemble des échantillons soient présents dans le coffret et que leur apparence est conforme comme indiqué dans la section ci-dessous. De plus assurez-vous qu'aucun des flacons ne soient brisés et en informer immédiatement votre représentant Randox si cela est le cas. Enfin, il est nécessaire de se connecter à www.riqas.net pour confirmer la date exacte à laquelle vous avez reçu ce kit.

CARACTÉRISTIQUES:

Ce coffret contient 6 sérums liquides en flacons de 1 ml, étiquetés 1 à 6.

DATE DE RETOUR:

Ces échantillons sont à tester de préférence à la date recommandée, et les résultats doivent nous parvenir au plus tard le lundi midi et selon le calendrier inclus dans le coffret de sérums ce contrôle. Vous pouvez envoyer vos résultats via Riqasnet ou par e.mail à l'adresse suivante: mail@riqas.com.

PREPARATION/STOCKAGE/STABILITE DES ECHANTILLONS:

Les échantillons sont prêts à l'emploi. Laisser les échantillons revenir à température ambiante avant l'analyse. Pour éviter toutes évaporation, placer le bouchon en plastique et fermer immédiatement après l'emploi et conserver entre +2 et +8°C. Une fois le flacon ouvert, l'analyse doit être faite dans les deux jours, conservés à 2-8°C. Les échantillons de contrôle doivent être traités comme les échantillons patients. Les échantillons doivent être conservés entre 2-8°C lorsqu'ils ne sont pas utilisés.

SÉCURITÉ :

Ces sérums sont d'origine humaine et sont contrôlés au niveau des donneurs pour s'assurer de l'absence de virus (Hépatite, HIV). Toutefois, il est recommandé de manipuler ces sérums avec précaution comme s'il s'agissait de sérums de patients.

Réservé uniquement pour un usage **IN VITRO**.

*** NOTE IMPORTANTE:** Les résultats **RIQAS** doivent parvenir au Département **RIQAS** au plus tard le lundi **17 heures GMT** selon la **DATE FINALE**. Nous vous recommandons d'analyser les échantillons quelques jours avant la date limite. **Les résultats en retard ne pourront pas être acceptés.**

Italiano

PROGRAMMA MENSILE PER PROTEINE SPECIFICHE: RQ9187

CONFERMA DELLE CARATTERISTICHE DEL KIT E DELLA DATA DI RICEZIONE

Si prega di confermare che sia presente il numero corretto di campioni e che i vostri campioni siano come indicato nella sezione CARATTERISTICHE qui sotto. Confermare che nessuna fiala sia rotta ed informare immediatamente il rappresentante Randox locale se ci fossero delle discrepanze. Infine, si prega di accedere al sito www.riqas.net per confermare la data esatta in cui si è ricevuto questo kit.

CARATTERISTICHE

La confezione contiene 6 fiale da 1 ml di campioni liquidi. Le fiale sono etichettate con il numero del campione.

PREPARAZIONE/CONSERVAZIONE/ STABILITA' DEI CAMPIONI

I campioni sono pronti all'uso. Lasciare che i campioni raggiungano la temperatura ambiente prima dell'analisi. Per evitare l'evaporazione, rimettere il tappo di gomma e chiudere la fiala immediatamente dopo l'uso. Una volta aperto, analizzare il campione entro 2 giorni se conservate a +2 - +8 °C. I campioni devono essere trattati come pazienti reali. I campioni, se non utilizzati, devono essere conservati a 2 - 8 °C.

SICUREZZA

Il siero è a base umana. È stato analizzato alla fonte, e ha dato esito negativo, per l'HBsAg e anticorpi dell'HIV. Tuttavia, al fine di assicurare una protezione completa, si raccomanda di manipolare il siero con la stessa cura riservata ai campioni dei pazienti.

Solo per uso **IN VITRO**.

*** NOTA IMPORTANTE:** I risultati devono arrivare a **RIQAS** entro le **17:00 GMT** (ora di Greenwich) della **DATA FINALE**. Se la **DATA DI ANALISI** **RACCOMANDATA** fosse troppo breve, si consiglia di analizzare il campione prima per rispettare la scadenza. I risultati inviati con ritardo superiore alla data finale per il campione successivo non saranno accettati.

Español

PROGRAMA MENSUAL DE PROTEINAS ESPECIFICAS: RQ9187

CONFIRMACION DE LAS CARACTERISTICAS DEL KIT Y LA FECHA DE RECEPCION.

Por favor, asegúrese de que ha recibido el numero correcto de muestras y que estas cumplen con la presentación indicada en la sección "CARACTERISTICAS" que encontrará a continuación. Por favor, confirme que ninguna de las muestras ha resultado dañada y contacte a su Representante local de Randox inmediatamente en el caso de que hubiese alguna discrepancia. Por ultimo, acceda a www.riqas.net para confirmar la fecha exacta en la que recibió el kit.

CARACTERISTICAS

El paquete contiene 6 frascos de muestras liquida de 1 ml. Las etiquetas de los frascos llevan indicado el número de muestra.

PREPARACIÓN/ ALMACENAMIENTO/ ESTABILIDAD DE LAS MUESTRAS

Las muestras están listas para usar. Dejar que las muestras alcancen temperatura ambiente antes de analizarlas. Para evitar la evaporación, colocar el tapón de goma y cerrar el frasco inmediatamente después de su uso y conservar entre +2 y +8°C. Una vez abierta, analice la muestra dentro de los 2 días siguientes **cundo son almacenados de +2 a +8 °C**. Las muestras deben ser tratadas de la misma manera que las muestras de los pacientes. Las muestras deben refrigerarse a 2-8 °C cuando no estén en uso.

SEGURIDAD

El suero es de base humana. El material de origen se ha analizado y encontrado negativo para HbsAg y anticuerpos de HIV. Sin embargo para una protección completa, se recomienda manejar el suero con el mismo cuidado que las muestras de pacientes.

Sólo para **IN VITRO**.

*** NOTA IMPORTANTE:** Los resultados deberán llegar a **RIQAS** antes de las **17:00 horas GMT** de la **FECHA FINAL**. Si la **FECHA DE ANALISIS** **RECOMENDADA** no le permite tiempo suficiente para la entrega de resultados, sugerimos se analice la muestra antes, para asegurarse de que pueden llegar antes del fin del plazo. Los resultados tardíos no serán aceptados después de la fecha final de la siguiente muestra.

Português

PROGRAMA MENSUAL DE PROTEÍNAS ESPECÍFICAS : RQ9187

CONFIRMAÇÃO DAS CARACTERÍSTICAS DO KIT E DATA DE RECEPÇÃO

Agradecemos-lhe que confirme que recebeu o número correcto de amostras e que estas têm o aspecto descrito na secção CARACTERÍSTICAS deste documento. Verifique também, se nenhum dos frascos está partido e notifique o seu representante local da Randox caso encontre alguma discrepância. Finalmente, acesse ao www.riqas.net para confirmar a data exacta em que recebeu este kit.

CARACTERÍSTICAS

A embalagem contém 6 frascos de 1 ml de amostras líquidas. Os frascos encontram-se rotulados com o número de amostra.

PREPARAÇÃO/CONSERVAÇÃO/ESTABILIDADE DAS AMOSTRAS

As amostras encontram-se prontas a usar. Deixar as amostras estabilizar à temperatura ambiente antes de analisar. Para evitar a evaporação, repor a tampa de borracha imediatamente após uso. Depois de aberto, analise a amostra dentro de 2 dias quando conservadas de +2 a +8°C. As amostras devem ser tratadas da mesma forma que as Amostras de Doentes. As amostras devem ser conservadas de -2 a -8 °C quando não estão a ser usadas.

SEGURANÇA

O soro é de matriz humana. Testes efectuados na origem confirmaram serem negativos para HBsAg e anticorpos HIV. No entanto para total protecção, recomenda-se que o soro seja manuseado como se de uma amostra de paciente se tratasse.

Somente para uso em **IN VITRO**.

*** NOTA IMPORTANTE:** Os resultados devem chegar ao **RIQAS** na **DATA FINAL** até às **17 horas, GMT**.

Se a **DATA RECOMENDADA PARA ANÁLISE** não permitir tempo suficiente para o envio, sugere-se que a amostra seja ensaiada antecipadamente, de forma a garantir o cumprimento do prazo final. Os resultados em atraso não serão aceites após a data final da amostra seguinte.

Dansk

MANED PROGRAM FOR SPECIFIKKE PROTEINER: RQ9187

BEKRÆFTELSE PÅ KIT KARAKTERISTIKA OG MODTAGELSESDATO

Du bedes kontrollere at det korrekte antal af prøver er tilstede i kittet og at prøverne ser ud som beskrevet i KARAKTERISTIKA-afsnittet nedenfor. Kontrollér venligst at alle flasker er intakte og kontakt straks din lokale Randox repræsentant, hvis der er uoverensstemmelser. Endelig, så bedes du logge på www.riqas.net og bekræfte datoen, hvor du modtog dette kit.

KARAKTERISTIKA

Pakningen indeholder 6 rør med 1 ml frysetørrede prøver. Rørene er mærket med prøvenummer.

FORBEREDELSE/OPBEVARING/STABILITET AF PRØVER

Prøverne er klar til brug. Lad prøven blive stuetemperatur før analyse. For at undgå fordampning skal gummiproppen genisættes, og røret skal lukkes umiddelbart efter brug og opbevares ved +2 til +8°C. Efter åbning bør prøverne analyseres indenfor 2 dage. . Prøverne skal behandles på samme måde som patientprøver. Prøverne skal opbevares ved -2 a -8 °C, når de ikke skal anvendes.

SIKKERHED

Serum er baseret på humane materialer. Kildematerialerne er blevet testet og fundet negative over for HBsAg og HIV-antistoffer. For komplet beskyttelse anbefales det imidlertid at håndtere serum med samme forsigtighed som patientprøver.

Kun beregnet til **IN VITRO**.

*** VIGTIG NOTE:** Resultaterne skal være RIQAS i hænde senest kl. 17.00 GMT på datoen for SENESTE FRIST. Hvis den ANBEFALEDE ANALYSESDATO ikke muliggør overholdelsen af dette, anbefaler vi at prøven analyseres før denne dato for at sikre at deadline overholdes. Forsinkede resultater vil ikke blive accepteret efter slutdatoen for den næste prøve.

Svenska

MANADS PROGRAM SPECIFIKA PROTEINER: RQ9187

ANKOMSTKONTROLL AV KIT EGENSKAPER OCH BEKRÄFTELSE AV LEVERANSDATUM

Kontrollera att korrekt antal prover (vialer) levererats och att proverna motsvarar nedan angivna egenskaper. Kontrollera att vialer är hela och oskadade. Meddela din lokala Randox distributör omedelbart om några avvikelser iaktas. Slutligen, vänligen logga in på www.riqas.net och bekräfta datum för mottagen leverans av detta kit.

INNEHÅLL

Förpackningen innehåller 6 flaskor med vardera 1 ml vätskeprov. Flaskorna är märkta med provnummer.

FÖRBEREDELSE/LAGRING/HÅLLBARHET PROVER (PROVERNAS STABILITET)

Proven är färdiga för användning. Pred analysen temperera materialen i rumtemperatur. För att undvika avdunstning, sätt tillbaka gummipropen och förslut flaskan omedelbart efter att den använts och förvara den vid +2 till +8°C. Prover analyseras inom 2 dagar efter att vialen öppnats. Proverna skall behandlas på samma sätt som patientprover. Proverna skall förvaras vid -2 a -8 °C när de inte används.

SÄKERHET

Serumet är humanbaserat. Det har ursprungstestats och befunnits vara negativt för HBsAg och för HIV-antikroppar. För fullständigt skydd rekommenderas att serumet hanteras lika försiktigt som ett patientprov.

Endast för **IN VITRO**.

*** VIKTIG ANMÄRKNING:** Resultaten måste vara **RIQAS** tillhanda per **17:00 GMT SLUTDATUMET**. Om **det REKOMMENDERADE ANALYSDATUMET** inte ger tillräckligt med tid så rekommenderar vi att provet analyseras tidigare, för att säkerställa att tidsgränsen kan klaras. Resultat som kommer in sent godtas inte efter slutdatumet för nästa prov.

Ελληνικά

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Tel: +44 (0) 28 9442 2413

Email: mail@riqas.com Website: www.randox.com

ΜΗΝΙΑΙΟ ΠΡΟΓΡΑΜΜΑ ΕΙΔΙΚΩΝ ΠΡΩΤΕΪΝΩΝ RQ9187

ΕΠΙΒΕΒΑΙΩΣΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΚΙΤ ΚΑΙ ΗΜΕΡΟΜΗΝΙΑΣ ΠΑΡΑΛΑΒΗΣ

Επιβεβαιώστε ότι έχετε παραλάβει το σωστό αριθμό δειγμάτων και ότι τα δείγματα σας έχουν την εμφάνιση, όπως αναφέρεται στην ενότητα ΧΑΡΑΚΤΗΡΙΣΤΙΚΑ παρακάτω. Επιβεβαιώστε ότι κανένα από τα φιαλίδια δεν είναι σπασμένο και ενημερώστε τον τοπικό αντιπρόσωπο της Randox αμέσως εάν κάτι δεν είναι σωστό. Τέλος, παρακαλώ συνδεθείτε στο www.riqas.net για να επιβεβαιώσετε την ακριβή ημερομηνία κατά την οποία λάβατε αυτό το κιτ.

ΧΑΡΑΚΤΗΡΙΣΤΙΚΑ

Το πακέτο περιέχει 6 φιαλίδια υγρών δειγμάτων 1 ml. Τα φιαλίδια φέρουν ετικέτα με τον αριθμό δείγματος.

ΠΡΟΕΤΟΙΜΑΣΙΑ / ΑΠΟΘΗΚΕΥΣΗ / ΣΤΑΘΕΡΟΤΗΤΑ ΔΕΙΓΜΑΤΩΝ

Τα δείγματα είναι έτοιμα για χρήση. Αφήστε τα δείγματα να φτάσουν σε θερμοκρασία δωματίου πριν από την ανάλυση. Για να αποφύγετε την εξάτμιση, ερμητοδομηθείτε το ελαστικό πώμα και κλείστε το φιαλίδιο αμέσως μετά από τη χρήση, και αποθηκεύστε σε θερμοκρασία από **+2 έως +8°C**. Απο όταν ανοιχθεί, το δείγμα πρέπει να αναλυθεί κατά τη διάρκεια 2 ημερών. τα δείγματα πρέπει να τα χειριζόμαστε όπως τα δείγματα ασθενών. Τα δείγματα πρέπει να αποθηκεύονται στους 2-8 °C όταν δεν χρησιμοποιούνται.

ΑΣΦΑΛΕΙΑ

Ο ορός έχει ανθρώπινη βάση. Έχει δοκιμαστεί στην πηγή και βρέθηκε αρνητικός για HBsAg και για αντισώματα σε HIV. Ωστόσο, για πλήρη προστασία, συνιστάται να μεταχειρίζεστε τον ορό με την ίδια προσοχή όπως και τα δείγματα ασθενών.

Μόνο για χρήση *IN VITRO*.

***ΣΗΜΑΝΤΙΚΗ ΣΗΜΕΙΩΣΗ:** Τα αποτελέσματα πρέπει να φθάσουν στην **RIQAS** μέχρι τις **17:00 GMT** στην **ΤΕΛΙΚΗ ΗΜΕΡΟΜΗΝΙΑ**. Εάν η **ΣΥΝΙΣΤΩΜΕΝΗ ΗΜΕΡΟΜΗΝΙΑ ΑΝΑΛΥΣΗΣ** δεν παρέχει επαρκή χρόνο, συνιστούμε το δείγμα να αναλύεται νωρίτερα ώστε να διασφαλιστεί η εμπρόθεσμη παραλαβή των αποτελεσμάτων. Καθυστερημένα αποτελέσματα δεν γίνονται δεκτά μετά την τελική ημερομηνία για το επόμενο δείγμα.

POLSKI

MIESIĘCZNY PROGRAM OZNACZANIA BIAŁEK SPECJALNYCH: RQ9187

POTWIERDZENIE CHARAKTERYSTYKI ZESTAWU I DATY ODBIORU

Prosimy o potwierdzenie, że zestaw zawiera odpowiednią ilość próbek i Państwa próbki wyglądają tak, jak w podanej poniżej CHARAKTERYSTYCE. Prosimy o potwierdzenie, że żadna z próbek nie jest zbita, a jeśli są jakiegokolwiek niezgodności prosimy o niezwłoczne zgłoszenie tego lokalnemu przedstawicielowi. Następnie prosimy o zalogowanie się na www.riqas.net w celu potwierdzenia dokładnej daty otrzymania zestawu.

CHARAKTERYSTYKA

Opakowanie zawiera 6 fiolek próbek płynnych po 1 ml. Fiolki są oznakowane numerem próbek.

PRZYGOTOWANIE/PRZECZYSZCZANIE/STABILNOŚĆ PRÓBEK

Próbki są gotowe do użycia. Pozwolić próbkom na osiągnięcie temperatury pokojowej przed analizą. Aby uniknąć odparowania, zdjąć gumowy korek i natychmiast zamknąć fiolkę po użyciu. Przechowywać w temperaturze od +2 do +8°C. Należy upewnić się, że próbka jest homogeniczna, delikatnie rolując ją w dłońmi. Proszę nie wstrząsać fiolką. Po otwarciu, wykonać oznaczenia w ciągu dwóch dni, jeżeli są przechowywane w temperaturze od +2 do +8° C. Próbki powinny być traktowane w ten sam sposób co próbki pacjentów. Próbki, kiedy nie są w użyciu powinny być przechowywane w temperaturze 2-8 °C.

BEZPIECZEŃSTWO

Surowica pochodzenia ludzkiego. Dawcy zostali przebadani i uznani za negatywnych jeśli chodzi o HbsAg i przeciwciała anty-HIV. Jednakże zaleca się aby postępować z surowicą tak samo jak z materiałami pobranymi od pacjentów.

Tylko do *in vitro*.

*** WAŻNA UWAGA:** Wyniki muszą nadejść do **RIQAS** przed **17:00 czasu GMT, OSTATNIEGO DNIA DATY FINALNEJ**. Jeżeli **ZALECANA DATA WYKONANIA OZNACZENIA** sprawia, że czasu jest zbyt mało, sugerujemy wcześniejsze przeprowadzenie oznaczenia, aby zdążyć przed datą finalną. Wyniki przesłane z opóźnieniem (po dacie finalnej), będą opracowywane jako spóźnione.

中文

每月特定蛋白质分析程序: RQ9187

产品包装与收件日期确认书 请确认您所收到的样本数量正确无误, 并且样本外观与下述“产品特性”中的内容描述一致
请确认您收到的样品瓶未发生破损等异常情况, 如有任何问题, 请立即联系朗道代表处
请您在收到本包装后登陆www.riqas.net确认收件具体日期

特性

本试剂包内装 6 瓶规格为 1 ml 的液态样本。试剂瓶上贴有样本编号。

样本的配制/储存/稳定性

样本开瓶即用。请分析前, 允许样本恢复至室温。为避免蒸发, 用后应立即用橡皮塞塞紧瓶子, 并贮藏于 +2 至 +8°C 条件下。开瓶后请在 2 天内检测。样本处理方法应与患者样本处理方法相同。样本在未使用时应置于 2-8°C 储存

安全

本血清源自人类血清。原料经过测试, 其 HBsAg 和 HIV 抗体呈阴性。但是, 为了更加全面地保护测试者, 建议将本血清当作患者样本小心处理。

只用于体外。

*** 重要注意事项:** 结果必须在“最终期限”当天 17:00 (格林威治时间) 之前送达 **RIQAS**。如果推荐分析日期所给时间不够, 建议提早分析样品以保证您能在规定时间内完成。将不接受在最终日期之后提交的结果。

Tiếng Việt

CHƯƠNG TRÌNH TRAO ĐỔI PROTEIN ĐẶC BIỆT HÀNG THÁNG: RQ9187

XÁC NHẬN VỀ NHỮNG ĐẶC TÍNH MẪU VÀ NGÀY NHẬN

Xin vui lòng xác nhận rằng bạn đã nhận đúng và đầy đủ số lượng mẫu, những mẫu đó được mô tả như phần "ĐẶC TÍNH" dưới đây. Xin vui lòng xác nhận không có lọ mẫu nào bị vỡ hoặc hư hỏng và thông báo ngay cho đại diện của hãng Randox tại địa phương của bạn nếu có sai lệch. Sau cùng, xin vui lòng đăng nhập vào www.riqas.net để xác nhận thời gian chính xác mà bạn đã nhận bộ mẫu này.

ĐẶC ĐIỂM

1 hộp bao gồm 6 lọ mẫu dạng lỏng, mỗi lọ 1 ml (6 x 1 ml) được đánh số thứ tự từ 1-6 theo số thứ tự mẫu phân tích

CHUẨN BỊ/BẢO QUẢN/ĐỘ BỀN CỦA MẪU

Mẫu phân tích có thể sử dụng liền khi mở nắp. Để các mẫu đạt nhiệt độ phòng trước khi phân tích. Để tránh bay hơi, đóng nút cao su và nắp lọ ngay lập tức sau khi sử dụng và bảo quản ở +2 - +8°C. Sau khi mở nắp, mẫu nên được phân tích trong vòng 2 ngày. Những mẫu này nên được xử lý giống như mẫu bệnh nhân. Những mẫu này nên được bảo quản ở nhiệt độ 2-8°C khi chưa sử dụng

ĐỘ AN TOÀN

Có khả năng độc hại về sinh học. Mẫu có nguồn gốc từ người và đều được kiểm tra âm tính với HIV, HbsAg. Tuy nhiên để bảo đảm an toàn tuyệt đối, mẫu này nên được xử lý và phân tích như mẫu bệnh nhân.

Chỉ dùng cho phân tích trong ống nghiệm. Không được hút mẫu bằng miệng. Tuân thủ các khuyến cáo thông thường yêu cầu trong quy trình xử lý hoá chất phòng xét nghiệm.

LƯU Ý QUAN TRỌNG:

Kết quả phân tích phải được gửi đến cho RIQAS trước 17:00 GMT ngày hạn chót gửi trả kết quả. Phòng xét nghiệm nên phân tích mẫu sớm trước ngày khuyến cáo phân tích mẫu nếu cần để đảm bảo thời gian gửi trả kết quả. Kết quả phân tích trễ sẽ không được chấp nhận sau hạn chót gửi trả kết quả của mẫu tiếp theo.

TÜRKÇE

AYLIK SPESİFİK PROTEİNLER PROGRAMI: RQ9187

KİT ÖZELLİKLERİNİN VE ULAŞMA TARİHİNİN DOĞRULANMASI

Lütfen doğru sayıda örneğin bulunduğunu ve örneklerin görünüşlerinin aşağıda ÖZELLİKLER bölümünde belirtildiği gibi olduğunu doğrulayınız. Lütfen şişelerden hiç birinin kırık olmadığını doğrulayınız ve eğer herhangi bir uygunsuzluk varsa derhal yerel RANDOX sorumlunuzu uyarınız. Son olarak, lütfen www.riqas.net 'e giriş yaparak bu kiti hatasız teslim aldığınız tarihi doğrulayınız.

ÖZELLİKLER

Paket; her biri 1 ml likit örnek içeren 6 şişeden oluşur. Şişeler, örnek numaraları ile etiketlenmiştir.

NUMUNE HAZIRLAMA / DEPOLAMA / NUMUNELERİN STABİLİTESİ

Örnekler kullanıma hazırdır. Analizden önce numunelerin oda sıcaklığına gelmesine izin verin. Buharlaşmayı önlemek için; kullanım sonrasında hemen plastik tıpayı takınız ve kapağını kapatarak +2 ve +8°C'de muhafaza ediniz. Lütfen, örneği açtıktan sonraki 2 gün içerisinde çalışınız. Örnekler, hasta örnekleri ile aynı şekilde muamele edilmelidir. Örnekler kullanılmadığı zaman 2-8°C'de muhafaza edilmelidir.

GÜVENLİK

Serum, insan kaynaklıdır. Kaynak testi yapılmış ve HBsAg ve HIV antikorları negatif bulunmuştur. Yine de; tam korunma için hasta örnekleriyle aynı titizlikle çalışılması önerilir.

Sadece **IN VITRO** kullanım içindir.

*** ÖNEMLİ NOT:** Sonuçlar, RIQAS'a **SON SONUÇ GÖNDERİM TARİHİ**'nde saat 17:00'de ulaşılmış olmalıdır. Eğer **ÖNERİLEN ANALİZ TARİHİ** sizin için uygun değilse, sonuç gönderim tarihine yetişmesi için için örneği daha erken analiz etmenizi öneririz. Geç sonuçlar, bir sonraki örneğin son sonuç gönderim tarihi sonrasında kabul edilmeyecektir.

SLOVENSKY

MONTHLY SPECIFIC PROTEINS PROGRAMME: RQ9187

POTVRDENIE CHARAKTERISTIKY KITU A DÁTUMU DORUČENIA

Prosím potvrdte doručenie správneho čísla vzorky a potvrdte, či vzhľad vzoriek zodpovedá charakteristike opisanej v sekcii nižšie. Prosím potvrdte, že žiadne fľaštičky nie sú rozbité, v opačnom prípade okamžite kontaktuje svojho obchodného zástupcu. Po prihlásení na www.riqas.net potvrdte a zadajte presný dátum, kedy Vám bol kit doručený.

CHARAKTERISTIKA

Balenie obsahuje 6 fľaštičiek kvapalných 1 ml vzoriek. Fľaštičky sú označené číslom vzorky.

PRÍPRAVA/SKLADOVANIE/STABILITA VZORIEK

Vzorky sú pripravené na použitie. Vzorec naj se ogreje na sobno temperature pred izvajanjem analiz. Aby sa predišlo vyparovaniu, ihneď po použití zavrite fľaštičky gumenou zátkou a skladujte pri +2 až +8°C. Po otvorení analyzujte vzorku do 2 dní. Narábajte so vzorkami ako so vzorkami pacientov. Ak sa vzorky nepoužívajú skladujte ich pri teplote 2-8°C.

BEZPEČNOSŤ

Sérum je na báze ľudského materiálu. Zdroj materiálu bol testovaný a bol označený ako negatívny na HBsAg a protilátky k HIV. Pre bezpečnosť je však odporúčané zaobchádzať so sérom opatrne rovnako ako so vzorkami pacientov.

Iba na **IN VITRO** použitie.

*** POZNÁMKA:** Výsledky musia byť odoslané do **RIQAS** do **17:00 Hod GMT** vo **FINÁLNY DÁTUM**. Ak **ODPORÚČANÝ DÁTUM ANALÝZY** neposkytuje dostatočný čas, odporúčame analýzu vzorky skôr aby sa zabezpečilo dodržanie termínu. Výsledky prijaté po finálnom termíne nebudú akceptované.

Nov 2023