Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

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Thromboplastin L
Istruzioni per l'uso

it

SCOPO PREVISTO

Il kit Thromboplastin L è concepito per l'esecuzione di dosaggi di emostasi basati sulla presenza di coaguli.

Il primo test del tempo di protrombina standardizzato venne messo a punto dal Dr. Armand Quick nel 1935. Attualmente, questo test è diventato il metodo basilare di screening della coagulazione per la diagnosi di deficienze congenite ed acquisite dei fattori di coagulazione del percorso estrinseco (fattori II, V, VII e X)[1,2]. Questo test viene utilizzato anche per l'induzione e il monitoraggio della terapia anticoagulante orale[3,4] e può essere impiegato per valutare la capacità di sintesi proteica del fegato in disordini epatici cronici o acuti.
Il kit Thromboplastin L è realizzato a partire da cervello di coniglio, ma rassomiglia il BCT umano in termini di basso indice di sensibilità internazionale (ISI). L'ISI del kit Thromboplastin L è approssimativamente pari a 1,1 ed è calibrato rispetto alla preparazione di riferimento internazionale dell'OMS[5]. Il kit Thromboplastin L è particolarmente indicato per il monitoraggio della terapia anticoagulante orale e, in combinazione con plasma carente del fattore appropriato, per la misurazione dell'attività del fattore nel percorso estrinseco. In presenza di ioni di calcio, la tromboplastina tissutale è un attivatore che dà inizio al percorso di coagulazione estrinseco. Quando una miscela di tromboplastina tissutale e di ioni di calcio viene aggiunta a normale plasma citrato, si attiva il meccanismo di coagulazione che porta alla formazione di un coagulo di fibrina. Qualora sussista una deficienza all'interno del percorso estrinseco, il tempo richiesto per la formazione del coagulo risulterà prolungato in funzione della gravità della deficienza.

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica in vitro - NON INGERIRE. Indossare un'adeguata attrezzatura protettiva personale durante la manipolazione di tutti i componenti del kit. Per conoscere i relativi simboli precauzionali e di pericolo, laddove pertinente, fare riferimento alla dichiarazione di sicurezza del prodotto. Smaltire i componenti conformemente alle normative locali vigenti.

COMPOSIZIONE

Componente	Contiene	Descrizione	Preparazione
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Tromboplastina liquida di cervello di coniglio contenente cloruro di calcio, stabilizzatori e conservanti.	La tromboplastina calcica liquida è pronta all'uso. Per eseguire dosaggi PT standard non è necessario altro calcio. Il contenuto della fiala deve essere miscelato accuratamente prima dell'uso (5 minuti su un rullo).

Ogni kit contiene un Istruzioni per l'uso.

Ogni kit contiene un inserto recante i valori di riferimento specifici per il lotto.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

In combinazione con la Thromboplastin L è possibile utilizzare i seguenti prodotti:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

CONSERVAZIONE, VITA UTILE E STABILITÀ

I reagenti non aperti sono stabili fino alla data di scadenza indicata se conservati nelle condizioni riportate sul flacone o sull'etichetta del kit.

Thromboplastin L — Le fiale aperte sono stabili per 2 mesi ad una temperatura compresa tra +2 e +8°C, per 5 giorni a +15°C (Sysmex CA-1500 on-board) e per 6 ore a +37°C (AC-4 on-board compresi il contenitore del reagente e il tappo). È possibile ottenere una stabilità d'uso di 7 giorni (Sysmex CA-1500).
NON CONGELARE. Ammassi consistenti di particelle o variazioni nei valori previsti possono essere indice di deterioramento del prodotto.

RACCOLTA E PREPARAZIONE DEI CAMPIONI

Nel corso dell'intera procedura è necessario utilizzare plastica o vetro siliconizzato. Il sangue (9 parti) deve essere raccolto in sodio citrato al 3,2% o al 3,8% come anticoagulante (1 parte). Separare il plasma in seguito a centrifugazione a 1500 x g per 15 minuti. Il plasma deve essere conservato a +18 – +24°C. I test devono essere completati entro 4 ore dalla raccolta dei campioni; in alternativa, il plasma può essere conservato congelato a -20°C per 2 settimane o a -70°C per 6 mesi. Decongelare rapidamente a +37°C prima di eseguire i test. Non conservare a +37°C per oltre 5 minuti[6].

PROCEDURA

Per un rilevamento accurato dell'INR si raccomanda di determinare l'ISI specifico del laboratorio per il reagente con il sistema di test in uso. A tale scopo si raccomanda il ISI Calibrant Plasma Set (REF 5519) di Helena Biosciences Europe[7,8]. Questa procedura deve essere eseguita per ogni nuovo lotto di reagente. L'INR Reference Set (REF 5490) di Helena Biosciences Europe deve invece essere utilizzato per rilevare eventuali spostamenti dell'ISI del sistema locale osservati in concomitanza con cambiamenti della temperatura del laboratorio e in seguito a manutenzione dello strumento, tra le altre variazioni locali.

Metodo Manuale

1. Miscelare un quantitativo di Thromboplastin L sufficiente a completare i test previsti per la giornata e incubare a +37°C per un massimo di 4 ore.
2. Preriscaldare 0,1 mL di plasma di prova a +37°C per 2 minuti.
3. Aggiungere al plasma 0,2 mL di reagente a base di tromboplastina appena miscelato, azionando contemporaneamente un cronometro.
4. Annotare il tempo di formazione del coagulo con un'approssimazione a 0,1 secondi.

Metodo Automatico

Fare riferimento al manuale utente dello strumento appropriato per istruzioni dettagliate oppure contattare Helena Biosciences Europe per le note applicative specifiche dello strumento.

INTERPRETAZIONE DEI RISULTATI

I risultati devono essere indicati con un'approssimazione a 0,1 secondi e le ripetizioni devono corrispondere con una tolleranza del 5%. I valori di %PT possono essere interpolati dal grafico di calibrazione (%PT dei plasmi di calibrazione PT vs. tempo di coagulazione rilevato), che, se tracciato su carta a doppia scala logaritmica, deve apparire sotto forma di linea retta.

I valori di INR possono essere calcolati utilizzando la seguente formula: INR = (Tempo di PT Paziente / Tempo di PT normale medio)[ISI]

Per una guida chiara sulle indicazioni per la gestione dei pazienti con warfarina fare riferimento a The British Society for Haematology per la loro edizione più aggiornata delle 'Linee guida sull'anticoagulazione orale con warfarina'. Al momento della stampa questa è la quarta edizione del 2011[9].

LIMITAZIONI

Si sconsiglia l'impiego di diluizioni seriali di un plasma di riferimento per la curva %PT, che infatti possono dare luogo a discrepanze dovute al basso livello di fibrinogeno nelle diluizioni del plasma di riferimento, che non compaiono invece nei campioni dei pazienti con livelli di fibrinogeno prevalentemente normali. Helena Biosciences Europe consiglia di utilizzare a questo scopo il kit 5504R %PT/Direct INR.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anomali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi.
Helena Biosciences Europe mette a disposizione i seguenti controlli utilizzabili con questo prodotto:

REF 5166	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

VALORI DI RIFERIMENTO

Per la sicurezza del paziente, è necessario che il sistema sia monitorato continuamente da un operatore qualificato. Per tale motivo ciascun laboratorio dovrà elaborare i propri range di riferimento. Ciò è particolarmente importante per la calibrazione dell'ISI locale. Con l'impiego della gamma di strumenti Sysmex, i valori normali che variano tra 11,50 - 14,80 secondi; 0,930 - 1,160 INR; 79,10 - 112,80 %PT sono ritenuti tipici.

CARATTERISTICHE PRESTAZIONALI

Le seguenti caratteristiche prestazionali sono state determinate da Helena Biosciences Europe o dai propri rappresentanti con l'utilizzo di uno strumento di coagulazione Sysmex CA-1500. Ciascun laboratorio dovrà pertanto elaborare i propri dati prestazionali.

Riproducibilità

Campione	Routine Control N		Routine Control A		Routine Control SA	
	SD	CV (%)	SD	CV (%)	SD	CV (%)
Ripetibilità	0,07	0,59	0,24	1,09	0,45	1,11
Tra le serie	0,10	0,63	0,16	0,75	0,49	1,20
Tra giorni	0,04	0,32	0,06	0,27	0,25	0,62
All'interno del dispositivo/laboratorio	0,12	1,07	0,29	1,35	0,72	1,75

Interferenze

La Thromboplastin L Helena non è sensibile ai livelli di eparina di oltre 2 U/mL. Utilizzando una soglia di interferenza del 5%, non risulta esservi alcuna significativa interferenza da parte dell'emoglobina a concentrazioni fino a 10 g/l. Utilizzando una soglia di interferenza del 5%, non risulta esservi alcuna significativa interferenza da parte della bilirubina a concentrazioni fino a 0,5 g/l per la Thromboplastin L. I test per le interferenze dei lipidi dimostrano che i livelli dei lipidi non influenzano direttamente il tempo di coagulazione del reagente fino a 3,75 g/l. Concentrazioni lipidiche superiori a questo valore impediscono il rilevamento del coagulo.

Confronto dei metodi

Si è eseguito un confronto su 268 campioni tra il tempo di coagulazione in secondi e i valori INR utilizzando la tromboplastina L e la tromboplastina LI. Si sono ottenute le seguenti correlazioni:

Thromboplastin L (secondi) = 0,9911x + 0,1036	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

BIBLIOGRAFIA

1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice. *Am. J. Med. Sci*, 190: 501.
2. Biggs R (1976) Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Edition, Blackwell Scientific Publications, London.
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6. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays; Approved Guideline, 5th edn. CLSI: H21-A5.
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9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition. *British Journal of Haematology*, 154(3): 311-324.

Thromboplastin L
Instrucciones de uso

es

USO PREVISTO

El uso previsto del kit Thromboplastin L es realizar ensayos de hemostasia basados en la coagulación.

La primera prueba estandarizada de la protrombina en una sola etapa fue desarrollada por el Dr. Armand Quick en 1935. Ahora se ha convertido en la prueba de cribado básico de la coagulación para el diagnóstico de deficiencias congénitas y adquiridas de factores de coagulación de la vía extrínseca (factores II, V, VII y X)[1,2]. Se usa también para la inducción y monitorización del tratamiento anticoagulante oral[3,4] y puede usarse para valorar la capacidad de síntesis de proteínas del hígado en trastornos hepáticos crónicos o agudos.
La Thromboplastin L tiene su origen en cerebro de conejo, pero se parece a la BCT humana en su bajo Índice de Sensibilidad Internacional (ISI). El ISI de Thromboplastin L es de aproximadamente 1,1 y se calibra contra el preparado de referencia internacional de la OMS[5]. La prueba de Thromboplastin L está especialmente adaptada a la monitorización del tratamiento anticoagulante oral y, conjuntamente con el plasma deficiente en el factor oportuno, la medición de la actividad de los factores en la vía extrínseca. La tromboplastina tisular, en presencia de iones calcio, es un activador que inicia la vía extrínseca de la coagulación. Cuando se añade una mezcla de tromboplastina tisular e iones calcio al plasma normal citratado, se activa el mecanismo de coagulación, conduciendo a un coágulo de fibrina. Si se produce una deficiencia dentro de la vía extrínseca, el tiempo necesario para la formación de coágulos se prolongará dependiendo de la intensidad de la deficiencia.

ADVERTENCIAS Y PRECAUCIONES

Los reactivos que contiene este kit son sólo para uso de diagnóstico *in vitro*. NO INGERIR. Lleve el equipo de protección personal adecuado cuando utilice todos los componentes del kit. Consulte la declaración de seguridad del producto para saber más sobre las indicaciones adecuadas de advertencia y riesgo. Desechar los componentes de conformidad con las normativas locales.

COMPOSICIÓN

Componente	Contiene	Descripción	Preparación
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Tromboplastina líquida de cerebro de conejo que contiene cloruro de calcio, estabilizadores y conservantes.	La tromboplastina líquida calcificada está lista para su uso. No es necesario más calcio para realizar pruebas estándar de PT. Los contenidos del vial se deben mezclar bien antes de utilizarlo (5 minutos en el rodillo).

Cada kit contiene instrucciones de uso.

Cada kit contiene valores de referencia específicos insertados del lote.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

Los siguientes productos se puede utilizar junto con la Thromboplastin L:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

ALMACENAMIENTO, CADUCIDAD Y ESTABILIDAD

Los reactivos no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en el vial o en la etiqueta del kit.

Thromboplastin L — Los viales abiertos permanecen estables durante 2 meses a una temperatura de entre +2 – +8°C, 5 días a una temperatura mayor a +15°C (en el Sysmex CA1500), y 6 horas a una temperatura mayor a +37°C (en el AC-4, incluido el contenedor del reactivo y el tapón). Se puede conseguir estabilidad multiuso de 7 días (Sysmex CA-1500).
NO CONGELAR. Los grumos grandes de partículas o los cambios en los valores esperados pueden indicar deterioro del producto.

RECOGIDA Y PREPARACIÓN DE LAS MUESTRAS

Debe usarse siempre plástico o vidrio siliconizado. Debe recogerse sangre (9 partes) en el anticoagulante citrato sódico al 3,2% o al 3,8% (1 parte). Separar el plasma después de la centrifugación a 1500 x g durante 15 minutos. El plasma debe conservarse a +18 – +24°C. Las pruebas deberían terminarse en 4 horas desde la recogida de las muestras o el plasma puede conservarse congelado a -20°C durante 2 semanas o -70°C durante 6 mes. Descongelar rápidamente a +37°C antes de realizar la prueba. No conservar a +37°C durante más de 5 minutos[6].

PROCEDIMIENTO

Para la comunicación exacta del INR, se recomienda determinar la ISI específica del laboratorio del reactivo con el sistema de prueba en uso. Se recomienda el ISI Calibrant Plasma Set de Helena Biosciences Europe (REF 5519) para este fin[7,8]. Esto debe realizarse para cada nuevo lote de reactivos. Debe usarse el Set de Referencia de INR de Helena Biosciences Europe (REF 5490) para comprobar las desviaciones en el ISI del sistema local que se han observado con cambios en la temperatura del laboratorio y el mantenimiento posinstrumental, entre otras variaciones locales.

Método Manual

1. Mezclar la cantidad suficiente de Thromboplastin L para completar la prueba anticipada para el día e incubar a +37°C durante un periodo de tiempo no superior a 4 horas.
2. Precaliente 0,1 mL del plasma de prueba a +37°C durante 2 minutos.
3. Añada 0,2 mL de reactivo de tromboplastina recién mezclado al plasma mientras pone en marcha simultáneamente un cronómetro.
4. observa el tiempo hasta la formación del coágulo procurando afinar en la décima 0,1 de segundo más próxima.

Método Automatizado

Consulte el manual del usuario del instrumento adecuado para instrucciones detalladas o póngase en contacto con Helena Biosciences Europe para notas de aplicación específicas del instrumento.

INTERPRETACIÓN DE LOS RESULTADOS

Los resultados deben comunicarse en los 0,1 segundos más próximos y las pruebas duplicadas deben estar de acuerdo entre sí dentro del 5%. Los valores de %TP pueden interpolarse a partir del gráfico de calibración (%TP de los plasmas de calibración del TP frente al tiempo de coágulo medido) que debe ser una línea recta cuando se representa en un papel de gráficos log-log.

Los valores de INR pueden calcularse usando la siguiente fórmula: INR = (Tiempo de TP Paciente / Tiempo de TP normal medio)[ISI]

Si necesita una guía clara de indicaciones y tratamiento de pacientes con warfarina, consulte The British Society for Haematology y su última edición de "Guidelines on oral anticoagulation with warfarin" que, en el momento de impresión de este documento, se encuentra en su cuarta edición de 2011[9].

LIMITACIONES

El uso de diluciones seriadas de un plasma de referencia para la curva de %TP no se recomienda, porque puede llevar a discrepancias producidas por el bajo fibrinógeno en las diluciones del plasma de referencia, que no se reflejan en las muestras de pacientes que tienen fundamentalmente niveles normales de fibrinógeno. Helena Biosciences Europe recomienda utilizar el kit 5504R %PT/INR directa a tal fin.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los controles normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos.
Helena Biosciences Europe suministra los siguientes controles disponibles para usar con este producto:

REF 5166	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y sistemas usados. Por esta razón, cada laboratorio debe establecer su propio intervalo normal. Esto es especialmente importante para la calibración local del ISI. Con la serie de instrumentos Sysmex, es frecuente que los valores normales varíen entre 11,50 - 14,80 segundos; 0,930 - 1,160 INR; 79,10 - 112,80 %PT.

CARACTERÍSTICAS FUNCIONALES

Las siguientes características de rendimiento han sido determinadas por Helena Biosciences Europe o sus representantes usando un instrumento de coagulación Sysmex CA-1500. Cada laboratorio debe establecer sus propios datos de rendimiento.

Reproductibilidad

Muestra	Routine Control N		Routine Control A		Routine Control SA	
	SD	CV (%)	SD	CV (%)	SD	CV (%)
Repetibilidad	0,07	0,59	0,24	1,09	0,45	1,11
Entre series	0,10	0,83	0,16	0,75	0,49	1,20
Entre días	0,04	0,32	0,06	0,27	0,25	0,62
En el dispositivo/laboratorio	0,12	1,07	0,29	1,35	0,72	1,75

Interferencias

Helena Thromboplastin L no detecta niveles de heparina inferiores a 2 U/mL. Con un umbral de interferencia del 5%, no hay interferencias significativas de hemoglobina en concentraciones de hasta 10 g/L. Con un umbral de interferencia del 5%, no hay interferencias significativas de bilirrubina en concentraciones de hasta 0,5 g/L para Thromboplastin L. La interferencia de lípidos demuestra que los niveles de lípidos no afectan directamente al tiempo de coagulación del reactivo hasta 3,75 g/L. Las concentraciones de lípidos superiores evitan detectar la coagulación.

Comparación del método

La comparación del tiempo de coagulación y los valores INR se determinó con tromboplastina L y tromboplastina LI en 268 muestras. Se obtuvieron las siguientes correlaciones:

Thromboplastin L (segundo) = 0,9911x + 0,1036	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

BIBLIOGRAFÍA

1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice. *Am. J. Med. Sci*, 190: 501.
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Тест-система "Жидкий тромбопластин"
инструкция

ru

НАЗНАЧЕНИЕ

Комплект Тест-система "Жидкий тромбопластин" предназначен для выполнения анализов гемостаза на основе кровяного сгустка.

Впервые стандартизированный одностадийный тест для определения протромбинового времени был предложен д-ром Армандом Квиком в 1935г. Сейчас он стал основным скрининговым тестом для диагностики врожденного и приобретенного дефицитов факторов свертывания крови по внешнему пути (факторы II, V, VII и X)[1,2]. Он также используется для мониторинга терапии оральными антикоагулянтами[3,4], а также может применяться и для оценки белок синтетической функции печени при не острых либо хронических заболеваниях.
Реагент приготовлен из экстракта ткани мозга кролика и по значению своего МИЧ (Международного Индекса Чувствительности) сопоставим со Стандартом Тромбопластина Британии (ВСТ – British Comparative Thromboplastin). МИЧ Жидкого тромбопластина примерно равен 1.1 и откалиброван относительно международного референса ВОЗ[5]. Жидкий тромбопластин особенно подходит для мониторинга терапии оральными антикоагулянтами и для измерения активности факторов внешнего пути свертывания(вместе с соответствующей фактор-дефицитной плазмой). Тканевый тромбопластин в присутствии йонов кальция является активатором внешнего пути свертывания крови. При добавлении смеси тканевого тромбопластина с кальцием к нормальной цитратной плазме активируется механизм её свертывания, приводящий к образованию фибринового сгустка. Если у пациента имеет место дефицит факторов внешнего пути, то время, необходимое для образования сгустка будет удлиняться прямо пропорционально степени дефицита факторов.

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Содержащиеся в данном наборе реагенты предназначены только для *in vitro* диагностики– НЕ ПРИНИМАТЬ ВНУТРЬ! При работе со всеми компонентами набора использовать соответствующие средства индивидуальной защиты. В случае необходимости см. свидетельство о безопасности изделия для ознакомления с соответствующими описаниями опасного воздействия и сведениями о мерах предосторожности. Удаление компонентов в отходы производите в соответствии с местными правилами.

СОСТАВ

Компоненты	Состав набора	Описание	Приготовление реагентов
Жидкий тромбопластин	2 x 5 мл (Кат.№ 5265HL) 8 x 5 мл (Кат.№ 5265L) 10 x 10 мл (Кат.№ 5267L)	Тромбопластин-кальциевая суспензия реагента из экстракта ткани мозга кролика, раствора хлорида кальция и стабилизаторов	Жидкий кальцинированный тромбопластин, готовый для использования. Для проведения теста ПВ дополнительный кальций не требуется. Содержимое флакона перемешать до использования (5 мин. на роллере)

Каждый набор содержит инструкцию по применению.

Вкладыш с указанием референсных значений к различным анализаторам и методам исследования, характерные для данного лота.

НЕОБХОДИМЫЕ КОМПОНЕНТЫ, НЕ ВКЛЮЧЕННЫЕ В КОМПЛЕКТ ПОСТАВКИ

Продукция ниже, которая может использоваться вместе с Тест-системой «Тромбопластин»:

Кат.№ 5519	Калибратор МИЧ
Кат.№ 5490	Контроль на МНО

ХРАНЕНИЕ, СРОК ГОДНОСТИ И УСТОЙЧИВОСТЬ

Невскрытые флаконы с реагентами хранятся до истечения срока годности в условиях, указанных на этикетке.

Жидкий тромбопластин — Вскрытые флаконы годны к применению в течение 2 месяцев при температуре хранения 2-8°С, 5 дней при 15°С (на борту Sysmex CA-1500) и 6 часов при 37°С (на борту AC-4, используя контейнер для реагентов с крышкой). Стабильность реагента на борту Sysmex CA-1500 - 7 дней.
НЕ ЗАМОРАЖИВАТЬ! Признаки ухудшения качества реагента: большое скопление частиц или отличия от ожидаемых значений могут означать ухудшение свойств реактива.

ОТБОР И ПОДГОТОВКА ОБРАЗЦОВ

Для работы следует использовать только пластиковые или силиконированные стеклянные пробирки. Кровь забирается в пробирку с цитратным антикоагулянтом (3,2% или 3,8% цитрат натрия) в соотношении 9 + 1. После центрифугирования при 1500 g, в течение 15 минут (использование других параметров должно проверяться лабораторией), полученную плазму необходимо отделить от форменных элементов крови. Плазму следует хранить при температуре +18 – +24°С. Тестирование должно быть проведено в течение 4 часов после забора образцов, либо плазму можно однократно заморозить и хранить при температуре -20°С в течение 2 недель или при -70°С в течение 6 месяцев. Перед проведением исследования плазму следует быстро разморозить при +37°С. Не держать плазму при +37°С более 5 минут[6].

ПРОЦЕДУРА

Для установления более точного МНО рекомендуется определить специфическое для лаборатории значение МИЧ (так называемый «локальный» МИЧ) для жидкого тромбопластина. Helena Biosciences Europe рекомендует для этих целей применить Калибратор МИЧ (Кат.№ REF 5519)[7,8]. Подобная процедура должна быть проведена для каждой новой партии реагентов. Контроль на МНО (Кат.№ REF 5490) используется для контроля изменения в «локальном» МИЧ, так как его значение может незначительно варьировать в зависимости от используемых приборов, а также изменений температуры в лаборатории и других локальных факторов.

Ручной Метод

1. Взять необходимое количество жидкого тромбопластина, необходимое для проведения тестирования в течение дня и инкубировать при 37ºС (но не более 4 часов).
2. Прогреть 0,1 мл тестируемой плазмы при +37°С в течение 2 минут.
3. Добавить 0,2 мл свежеприготовленной рабочей смеси реагентов к плазме и немедленно включить таймер.
4. Заметить время, необходимое для образования сгустка с точностью до 0,1сек.

Автоматизированный Метод

Для проведения тестирования на автоматических коагулометрах, необходимо обратиться к руководству пользователя и к соответствующей адаптации, которые доступны у официальных дистрибьюторов и компании Хелена.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

Результаты должны быть представлены с точностью до 0,1 сек и разница в повторах не должна превышать 5%. Значение %ПВ можно определить по калибровочному графику (график зависимости %ПВ от измеренного времени), который должен быть строго линейным в билогарифмических координатах при построении графика на миллиметровке с логарифмическим масштабом на обеих осях.

МНО может быть вычислено по формуле: МНО= (ПВ (пациента)/среднее ПВ (норма))[МИЧ]

Для более подробной информации по мониторингу пациентов на Варфарине обратитесь к рекомендациям Британского Общества по Гематологии - «Рекомендации по антикоагулянтной терапии варфарином», 4-е издание 2011г, на время печати этого документа[9].

ОГРАНИЧЕНИЯ

Для получения графика зависимости (%ПТ) от времени свертывания не рекомендуется использовать серии разведений референсной плазмы, поскольку это может привести к неточности, вызванной низким содержанием фибриногена в больших разведениях референсной плазмы, что не соответствует образцам пациентов, имеющих, в основном, нормальный уровень фибриногена. Компания Хелена рекомендует использовать калибратор кат. номер 5504R для %ПВ, и прямого определения МНО.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными.
Компания Хелена рекомендует следующие контрольные материалы:

Кат.№ 5166	Контроль качества, норма
Кат.№ 5187	Контроль качества, умеренно выраженная патология
Кат.№ 5183	Контроль качества, высокая патология
Кат.№ 5490	Контроль на МНО

НОРМАЛЬНЫЕ ПОКАЗАТЕЛИ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и анализаторов. В связи с этим каждая лаборатория должна определить свою собственную область нормальных значений. Это крайне важно для установки локального МИЧ тромбопластина. Диапазон нормальных значений пациентов 11,50 - 14,80 сек.; 0,930 - 1,160 INR; 79,10 - 112,80 %PT с использованием коагулометров Sysmex.

ЭКСПЛУАТАЦИОННЫЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие приблизительные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики. При использовании оптико-механического коагулометра и реагентов Хелена были определены следующие коэффициенты вариации (CV):

Воспроизводимость

Образец	Контроль качества, норма		Контроль качества, умеренно выраженная патология		Контроль качества, высокая патология	
	SD	CV (%)	SD	CV (%)	SD	CV (%)
Воспроизводимость	0,07	0,59	0,24	1,09	0,45	1,11
в пределах аналитической серии	0,10	0,83	0,16	0,75	0,49	1,20
между разными аналитическими сериями	0,04	0,32	0,06	0,27	0,25	0,62
между партиями/лабораториями	0,12	1,07	0,29	1,35	0,72	1,75

Тест-система "Жидкий тромбопластин" не чувствителен к гепарину в концентрации до 2 Ед/мл. Используя 5% допустимое отклонение, реагент не чувствителен к гемоглобину в концентрации до 10 г/л. Используя 5% допустимое отклонение, реагент не чувствителен к билирубину в концентрации до 0,5 г/л. Не обнаружено чувствительности к уровню липидов до 3,75 г/л оказывающих воздействие на время свёртываемости. Концентрации липидов выше этого уровня предотвратит обнаружение сгустка.

Сравнение по стандартам:

Сравнение значений МНО 268 образцов, определённых с помощью Тест-системы "Тромбопластин" и Тест-системы "Жидкий тромбопластин" дало следующие корреляционные соотношения:

Жидкий Тромбопластин (сек) = 0,9911x + 0,1036	r^2 = 0,9941	n = 268
Жидкий Тромбопластин (МНО) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

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Declaration of Conformity

HL-7-0567DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5376R	Clauss Fibrinogen 100	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

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Signed:

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SAFETY DECLARATION

Product Description	**Clauss Fibrinogen 100**
Product Code	**5376R**

The product as received is an IVD kit containing the following materials:

Product Code	Product Description	SDS Product Identifier
HL-3-0606SA	Thrombin: 100 NIH/mL 2 mL	HL-6-0695MS
HL-3-2421SA	Imidazole Buffer 25 mL	HL-6-1081MS
HL-3-1110SA	Fibrinogen Calibrator 1 mL	N/A
HL-3-2115SA	Kaolin Suspension: 0.5 g/L 5 mL	N/A

Each material has been assessed for the chemicals used in its manufacture. Please refer to the table above for the SDS of materials that contain hazardous materials at a concentration that requires hazard warnings to be applied to the label and/or hazard statement.

If the product contains additional materials which were found to contain no hazardous substances or contain them at concentrations or quantities less than those requiring classification under EU regulation 453/2010 or EU regulation 1272/2008, these are defined as not applicable (N/A).

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Тест-система "Определение фибриногена методом Клаусса 100"
инструкция

ru

ПРИМЕНЕНИЕ

Тест-система "Определение фибриногена методом Клаусса 100" предназначена для проведения количественного определения фибриногена по Клауссу в плазме крови человека на коагулометрах. Метод Клаусса[1] – простой метод количественного определения фибриногена, основанный на измерении времени образования сгустка. Метод проводится в разведенной плазме после добавления тромбинового реагента (> 30 МЕ/мл). Время образования сгустка пропорционально концентрации фибриногена. Уровень фибриногена может увеличиваться при воспалении, беременности или при приеме пероральных контрацептивов[2]. Низкие значения могут наблюдаться при заболеваниях печени и ДВС. Изменение содержания фибриногена в плазме помогает диагностике врожденных дефицитных состояний, включая афибриногенемию (полное отсутствие фибриногена), гипофибриногенемию (концентрация фибриногена менее 1 мг/мл) и дисфибриногенемию (структурные нарушения в молекуле фибриногена).

ПРЕДУПРЕЖДЕНИЯ И ПРЕДОСТОРОЖНОСТИ

Реактивы, содержащиеся в наборе, предназначены только для *in-vitro* диагностики. При работе с любым из компонентов набора применяйте соответствующую защитную одежду (одноразовые резиновые или пластиковые перчатки и т.д.). Ознакомьтесь с инструкцией по мерам предосторожности. Тестирование контрольной плазмы (либо реагента) на содержание антигена вируса гепатита B (HBsAg), антител к HIV I и II антител и HCV дало отрицательный результат (за исключением, если последнее не указано на упаковке или флаконе), тем не менее, при работе с ней/ним следует соблюдать такую же осторожность, как и при работе с образцами плазмы крови человека.
Не рекомендуется использовать на Helena C-1/2/4/AC-4.

СОСТАВ РЕАГЕНТОВ

Компоненты	Состав набора	Описание	Приготовление реагентов
Тромбиновый Реагент: 100 МЕ/мл	5 x 2 мл (Кат. № 5376R) 5 x 1 мл (Кат. № 5376HR)	содержит 200 единиц (Кат. № 5376R) / 100 единиц (Кат. № 5376HR) бычьего тромбина со стабилизаторами.	Внести во флакон: 2.0 мл (Кат. № 5376R) или 1.0 мл (Кат. № 5376HR) дистиллированной (деионизированной воды) или каолиновой суспензии (0,5 г/л) в зависимости от адаптации к прибору. Осторожно перемешать и оставить при комнатной температуре в течение 15 минут. Перед использованием еще раз перемешать. Не встряхивать.
Калибратор Фибриногена	2 x 1 мл (Кат. № 5376R) 1 x 1 мл (Кат. № 5376HR)	Содержит 1,0 мл лиофилизированной нормальной плазмы человека, аттестованной по уровню фибриногена.	Внести во флакон 1.0 мл дистиллированной или деионизированной воды. Осторожно перемешать и оставить при комнатной температуре в течение 10 минут. Перед использованием еще раз перемешать. Не встряхивать.
Буфер Имидазоловый	2 x 25 мл (Кат. № 5376R) 1 x 25 мл (Кат. № 5376HR)	В каждом флаконе содержится водный раствор 0.05М Имидазола, натрия хлорид и азид натрия, <0.1%, в качестве консерванта pH=7.3 ±0.10.	Дополнительные разведения не требуются.
Каолиновая суспензия 0.5 г/л	2 x 5 мл (Кат. № 5376R) 1 x 5 мл (Кат. № 5376HR)	Содержит 5 мл каолиновой суспензии с концентрацией 0.5 г/л.	Перед использованием перемешать. Не встряхивать. Убедитесь в растворение осажденного материала.

Каждый набор содержит инструкцию по применению.
Паспорт с референсными значениями.

ТРЕБУЕМЫЕ, НО НЕ ПОСТАВЛЯЕМЫЕ МАТЕРИАЛЫ

Тест-система "Определение фибриногена методом Клаусса 100" может использоваться на любом коагулометре метод количественного определения фибриногена по Клауссу. (Не рекомендуется использовать на Helena C-1/2/4/AC-4). Адаптации реагентов к различным приборам доступны по запросу у официальных дистрибьюторов и компании Хелена.
Реагенты, входящие в набор могут быть заказаны отдельно:

Кат. № 5374	Тест-система "Фибриноген по Клауссу (только тромбиновый реагент)"
Кат. № 5378	Тест-система "Фибриноген по Клауссу (только тромбиновый реагент)"
Кат. № 5379	Калибратор фибриногена
Кат. № 5375R	Буфер Имидазоловый
Кат. № 050-920	Тестовый реагент "Фибриноген по Клауссу, суспензия оптическая"

ХРАНЕНИЕ И СТАБИЛЬНОСТЬ

Невскрытые флаконы хранятся до истечения срока годности в условиях, указанных на упаковке или этикетке.

Тромбиновый: 100 МЕ/мл	После растворения, тромбиновый реагент стабилен в течение 7 дней при +2 –+8°C, 8 часов на борту анализатора при +15 –+30°C и 1 месяц при -20°C.
Калибратор Фибриногена	После растворения, калибратор стабилен в течение 4 часов при +2 –+8°C.
Буфер Имидазоловый	Вскрытый флакон с буфером следует хранить при +2 –+8°C.
Каолиновая суспензия	Вскрытый флакон с буфером следует хранить при +2 –+8°C.

СБОР И ПРИГОТОВЛЕНИЕ ОБРАЗЦОВ

Для работы следует использовать только пластиковые или силиконированные стеклянные пробирки. Кровь забирается в пробирку с цитратным антикоагулянтом (3,2% или 3,8% цитрат натрия) в соотношении 9 + 1. После центрифугирования при 1500 g, в течение 15 минут (использование других параметров должно проверяться лабораторией), полученную плазму необходимо отделить от форменных элементов крови. Плазму следует хранить при температуре +2 –+8°C или +18 –+24°C. Тестирование должно быть проведено в течение 4 часов после забора образцов, либо плазму можно однократно заморозить и хранить при температуре -20°C в течение 2 недель или при -70°C в течение 6 месяцев. Перед проведением исследования плазму следует быстро разморозить при +37°C. Не держать плазму при +37°C более 5 минут[3].

ПРОЦЕДУРА ВЫПОЛНЕНИЯ АНАЛИЗА

Ручной Метод

1. Подготовьте все реактивы, см. выше раздел Приготовление реагентов.
2. Новая калибровка должна использоваться при изменении номера партии реагентов или если ожидаемые значения контроля выходят за пределы референсных значений. Разведите калибратор Буфер Имидазоловый как указано в таблице:

Пробирки	Разведение	Калибратор Фибриногена (мл)	Буфер (мл)
1	1 + 4	0,2	0,8
2	1 + 9	0,1	0,9
3	1 + 19	0,1	1,9
4	1 + 29	0,1	2,9
5	1 + 39	0,1	3,9

3. Подготовка образца:
   а Смешайте 1 часть плазмы пациента или контроля с 9 частями Буфер Имидазоловый
   б Аккуратно перемешайте (без встряхивания).
4. Выполняйте все тесты в дубле:
   а Отберите пипеткой 0,2 мл стандарта, пробы пациента или контроля в реакционную пробирку и инкубируйте в течение 2 минут при +37°C.
   б Добавьте 0,1 мл тромбинового реактива (+15 –+30°C).
   в Определите время свертывания с точностью 0,1 секунды.
   г На миллиметровой бумаге (вложенной в набор реагентов) отложите по оси Y значения: (концентрация фибриногена), а по оси X значения: (время свертывания стандарта).
   д Должна быть получена прямая линия. Определите значения калибратора фибриногена в разведении 1+9, интерполируйте полученное значение с целью контроля стандартной кривой.

Автоматизированный Метод

Для получения более подробной информации обратитесь к инструкции на автоматический или полуавтоматический коагулометр.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

Средний уровень Фибриногена в популяции практически здоровых людей находится между 150-350 мг/дл (1.5-3.5 г/л)[4,5].

ОГРАНИЧЕНИЯ

На низко ложные результаты концентрации фибриногена, полученные на коагулометре, может влиять гепарин в концентрации >0.6 Ед/мл и ПДФ в концентрации >100 мг/мл. Если значения образцов пациентов выпадают за график стандартной кривой, то требуется дальнейшее разведение образца, чтобы значение попадали в линейный диапазон от 1,0 до 6,5 г/л.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными. компания Хелена рекомендует следующие контрольные материалы:

Кат. № 5301	Контроль качества специальные тесты, норма
Кат. № 5302	Контроль качества специальные тесты, патология
Кат. № 5186	Контроль качества, норма
Кат. № 5187	Контроль качества, умеренно выраженная патология
Кат. № 5183	Контроль качества, высокая патология

РЕФЕРЕНСНЫЕ ЗНАЧЕНИЯ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и коагулометров. По этой причине каждая лаборатория должна установить свои собственные значения.

АНАЛИТИЧЕСКИЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие ориентировочные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики. При использовании ручного метода были определены следующие коэффициенты вариации (CV) и линейность в диапазоне от 1,0 до 6,5 г/л (без дополнительных разведений плазмы).

Воспроизводимость

в пределах аналитической серии			между разными аналитическими сериями		
Фибриноген (г/л)	*n*	*CV (%)*	*Фибриноген (г/л)*	*n*	*CV (%)*
1.24	5	4.88	1.02	10	6.17
3.01	5	3.58	3.62	10	3.75

СПИСОК ЛИТЕРАТУРЫ

1. Clauss A (1957) Gerinnungsphysiologische Schnell-methode zur bestimmung des Fibrinogens, *Acta Haematol*, **17**:237-246
2. Shaw TS (1977) Assays for Fibrinogen and its Derivatives CRC, *Crit. Rev. Clin. Lab. Sci*, **8**:145-192.
3. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5
4. Scully RE *et al.* (1980) Normal Reference Laboratory Values, *New England Journal Medcine*, **302**(37):37-48.
5. Okuno T, Selenko V (1972) Plasma fibrinogen determination by automated thrombin time, *American Journal of Medical Technology*, **38**(6):195-201

Declaration of Conformity

HL-7-0137DC DOI 2015/07 (7)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 28 Jul 2015

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Declaration of Conformity

HL-7-0138DC DOI 2015/07 (7)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

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Declaration of Conformity

HL-7-0135DC DOI 2015/07 (7)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

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REFERENZWERTE

Referenzwerte können je nach Technik und verwendetem System von Labor zu Labor unterschiedlich sein. Aus diesem Grund sollte jedes Labor seine eigenen Referenzwertbereiche erstellen.

LEISTUNGSMERKMALE

Die folgenden Leistungseigenschaften wurden von Helena Biosciences Europe oder in ihrem Auftrag mit einem optomechanischen Gerinnungsgerät ermittelt. Jede Labor muss seine eigenen Werte ermitteln.

Reproduzierbarkeit

		Intra-assay-Präzision	
Probe	***n***	***aPTT CV (%)***	***PT CV (%)***
Routine Control N	5	2.83	1.01
Routine Control A	5	2.76	1.71
Routine Control SA	5	1.72	1.03

LITERATURVERZEICHNIS

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology*, 37:559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, 55:561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP*, 59:231-235.

Plasmi di controllo della coagulazione
Istruzioni per l'uso

it

SCOPO PREVISTO

Il kit Coagulation Control Plasmas è concepito per l'uso come materiale di controllo qualità.

Routine Control N, Routine Control A e Routine Control SA sono destinati ad essere utilizzati come controlli normali, moderatamente prolungati e marcatamente prolungati per i dosaggi di PT e aPTT. Essi vengono dosati anche per fibrinogeno, TCT e ATIII e sono preparati con plasma umano normale.

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica *in vitro* - NON INGERIRE. Indossare un'adeguata attrezzatura protettiva personale durante la manipolazione di tutti i componenti del kit. Per conoscere i relativi simboli precauzionali e di pericolo, laddove pertinente, fare riferimento alla dichiarazione di sicurezza del prodotto. Smaltire i componenti conformemente alle normative locali vigenti.

I prodotti ematici sono stati sottoposti a screening e trovati negativi (salvo diversa indicazione sulla confezione del kit o sulla fiala) per la presenza di:
Antigene dell'epatite B (HbsAg)
Anticorpo HIV 1
Anticorpo HIV 2
Anticorpo HCV
Questi prodotti devono tuttavia essere manipolati con le stesse misure precauzionali adottate per un campione paziente umano.

COMPOSIZIONE

REF	Componente	Contiene	Descrizione
5186	Routine Control - N	10 x 1 mL	Preparato con un pool di plasma normale.
5187	Routine Control - A	10 x 1 mL	Preparati con plasma umano adsorbito.
5183	Routine Control - SA	10 x 1 mL	Preparati con plasma umano adsorbito.
5482	Routine Coagulation Control Set:		
	Routine Control - N	4 x 1 mL	
	Routine Control - A	3 x 1 mL	
	Routine Control - SA	3 x 1 mL	

Ogni kit contiene un istruzioni per l'uso.
Ogni kit contiene un inserto recante i valori di riferimento specifici per il lotto.

Ogni flacone contiene 1 mL di plasma umano tamponato liofilizzato.

Preparazione: Ricostituire ogni flacone di controllo appropriato con 1 mL di acqua distillata o deionizzata. Agitare delicatamente. Attendere 10 minuti per consentire al prodotto di sciogliersi completamente e miscelare bene prima dell'uso.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

Il Coagulation Control Plasmas può essere utilizzato durante l'esecuzione di test su qualsiasi strumento di coagulazione meccanico o foto-ottico in combinazione con tutti i reagenti idonei disponibili in commercio.

CONSERVAZIONE, VITA UTILE E STABILITÀ

Ogni riferimento a nomi e dati utilizzati negli esempi è casuale, se non specificato diversamente. I controlli ricostituiti sono stabili per 8 ore se conservati a °2 —°8°C oppure 4 settimane a -20°C se congelato molto velocemente. Mantenere i prodotti coperti.

RACCOLTA E PREPARAZIONE DEI CAMPIONI

Non applicabile.

PROCEDURA

Ogni controllo deve essere trattato seguendo la stessa procedura adottata per il campione non noto, conformemente alle istruzioni riportate in ciascun protocollo di test specifico.

INTERPRETAZIONE DEI RISULTATI

Routine Control N deve fornire valori compresi nel range normale di laboratorio per i dosaggi di PT, aPTT e fibrinogeno. Routine Control A e Routine Control SA sono stati standardizzati per fornire, rispettivamente, tempi di PT e aPTT prolungati e marcatamente prolungati. I valori previsti specifici per il lotto e lo strumento vengono forniti con ciascuna confezione di controlli.

LIMITAZIONI

I risultati ottenuti con il Coagulation Control Plasmas dipendono da innumerevoli fattori, strettamente legati alla strumentazione, ai tipi di reagenti, a substrati carenti e alle variazioni dovute ai singoli laboratori[1,2,3]. Ogni laboratorio dovrà definire un range di previsione per il sistema strumento-reagente specificamente utilizzato.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anormali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi.

VALORI DI RIFERIMENTO

Per la sicurezza del paziente, è necessario che il sistema sia monitorato continuamente da un operatore qualificato. Per tale motivo ciascun laboratorio dovrà elaborare i propri range di riferimento.

CARATTERISTICHE PRESTAZIONALI

Le seguenti caratteristiche prestazionali sono state determinate da Helena Biosciences Europe o dai propri rappresentanti con l'utilizzo di uno strumento di coagulazione opto-meccanico. Ciascun laboratorio dovrà pertanto elaborare i propri dati prestazionali.

Riproducibilità

		Precisione intra-dosaggio	
Campione	***n***	***aPTT CV (%)***	***PT CV (%)***
Routine Control N	5	2.83	1.01
Routine Control A	5	2.76	1.71
Routine Control SA	5	1.72	1.03

BIBLIOGRAFIA

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology*, 37:559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, 55:561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP*, 59:231-235.

Plasmas de control de la coagulación
Instrucciones de uso

es

USO PREVISTO

El uso previsto del kit Coagulation Control Plasmas es como material de control de calidad.

Routine Control N, Routine Control A y Routine Control SA se usan como controles normal, moderadamente prolongado y notablemente prolongado para las valoraciones de TP y TTPa. También se valoran para fibrinógeno, TCT y ATIII y se elaboran a partir de plasma humano normal.

ADVERTENCIAS Y PRECAUCIONES

Los reactivos que contiene este kit son sólo para uso de diagnóstico *in vitro*. NO INGERIR. Lleve el equipo de protección personal adecuado cuando utilice todos los componentes del kit. Consulte la declaración de seguridad del producto para saber más sobre las indicaciones adecuadas de advertencia y riesgo. Desechar los componentes de conformidad con las normativas locales.

La sangre se ha sometido a pruebas que han resultado negativas (a menos que se indique lo contrario en la caja del kit o en el vial) de la presencia de:
Antígeno de la hepatitis B (HbsAg)
Anticuerpos del VIH 1
Anticuerpos del VIH 2
Anticuerpos del VHC
Sin embargo, deben manipularse con las mismas precauciones que una muestra de un paciente.

COMPOSICIÓN

REF	Componente	Contiene	Descripción
5186	Routine Control - N	10 x 1 mL	Elabora a partir de plasma normal de reserva.
5187	Routine Control - A	10 x 1 mL	Elaboran a partir de plasma humano adsorbido.
5183	Routine Control - SA	10 x 1 mL	Elaboran a partir de plasma humano adsorbido.
5482	Routine Coagulation Control Set:		
	Routine Control - N	4 x 1 mL	
	Routine Control - A	3 x 1 mL	
	Routine Control - SA	3 x 1 mL	

Cada kit contiene instrucciones de uso.
Cada kit contiene valores de referencia específicos insertados del lote.

Cada vial contiene 1 mL de plasma humano tamponado, liofilizado.

Preparación: Reconstituya cada vial del control adecuado con 1 mL de agua destilada o desionizada. Agite suavemente. Deje que repose durante 10 minutos para que la disolución sea completa y mezcle bien antes de su uso.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

El Coagulation Control Plasmas puede usarse cuando se realizan pruebas con cualquier instrumento de coagulación mecánica o foto-óptica junto con todos los reactivos adecuados, comerciales.

ALMACENAMIENTO, CADUCIDAD Y ESTABILIDAD

Los viales no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en el vial o en la etiqueta del kit. Los controles reconstituidos son estables durante 8 horas cuando se conservan a °2 —°8°C o durante 4 semanas a -20°C cuando se conserva con congelación instantánea. Manténgase cubierto.

RECOGIDA Y PREPARACIÓN DE LAS MUESTRAS

No aplicable.

PROCEDIMIENTO

Cada control debe tratarse de la misma forma que la muestra desconocida, de acuerdo con las instrucciones indicadas en cada protocolo de prueba concreto.

INTERPRETACIÓN DE LOS RESULTADOS

Routine Control N debe dar valores dentro del intervalo normal de laboratorio para TP, TTPa y valoraciones de fibrinógeno. El Routine Control A y el Routine Control SA han sido estandarizados para dar tiempos de TP y TTPa prolongados y notablemente prolongados, respectivamente. Se aportan los valores esperados específicos de lote y de instrumento con cada paquete de controles.

LIMITACIONES

Los resultados obtenidos con Coagulation Control Plasmas dependen de varios factores fuertemente asociados a la instrumentación, los tipos de reactivos, sustratos deficientes y variaciones entre laboratorios[1,2,3]. Cada laboratorio debe establecer un intervalo esperado para el sistema instrumento-reactivo concreto.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los plasmas de control normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos.

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y sistemas usados. Por esta razón, cada laboratorio debe establecer sus propios intervalos de referencia.

CARACTERÍSTICAS FUNCIONALES

Las siguientes características de rendimiento han sido determinadas por Helena Biosciences Europe o sus representantes usando un instrumento de coagulación opto-mecánico. Cada laboratorio debe establecer sus propios datos de rendimiento.

Reproducibilidad

		Precisión intra-ensayo	
Muestra	***n***	***TTPa CV (%)***	***TP CV (%)***
Routine Control N	5	2.83	1.01
Routine Control A	5	2.76	1.71
Routine Control SA	5	1.72	1.03

BIBLIOGRAFIA

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology*, 37:559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, 55:561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP*, 59:231-235.

КОНТРОЛЬНЫЕ ПЛАЗМЫ
инструкция

ru

НАЗНАЧЕНИЕ

Комплект Coagulation Control Plasmas предназначен для использования в качестве материала для контроля качества.

Контрольные плазмы: «Контроль качества, норма», «Контроль качества, высокая патология», «Контроль качества, умеренно выраженная патология» – контроли качества с нормальным, умеренно увеличенным и значительно увеличенным активированным парциальным тромбопластиновым временем (АПТВ/АПТВ) и протромбиновым временем (ПВ). Их также можно использовать для определения количества фибриногена, тромбинового времени (ТВ) и антитромбина III (АТ-III). Контроли приготовлены из человеческой плазмы практически здоровых людей.

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Содержащиеся в данном наборе реагенты предназначены только для *in vitro* диагностики– НЕ ПРИНИМАТЬ ВНУТРЬ! При работе со всеми компонентами набора использовать соответствующие средства индивидуальной защиты. В случае необходимости см. свидетельство о безопасности изделия для ознакомления с соответствующими описаниями опасного воздействия и сведениями о мерах предосторожности. Удаление компонентов в отходы производите в соответствии с местными правилами.

Препараты крови были подвергнуты скринингу и показали отрицательный результат (если на коробке, в которую упакован комплект или на пробирке не указано иное) на:
Антиген к гепатиту B (HbsAg)
Антитела к ВИЧ 1
Антитела к ВИЧ 2
Антитела к вирусу гепатита C (HCV)
Тем не менее с ними следует обращаться, соблюдая те же меры предосторожности, что и при обращении с образцом, полученным от человека.

СОСТАВ

Кат. №	Компоненты	Состав набора	Описание
5186	Контроль качества, норма	10 x 1 мл	приготовлен из пула нормальной плазмы.
5187	Контроль качества, умеренно выраженная патология	10 x 1 мл	приготовлен из адсорбированной плазмы.
5183	Контроль качества, высокая патология	10 x 1 мл	приготовлен из адсорбированной плазмы.
5482	Контроль коагуляции, уровень П1:		
	Контроль качества, норма	4 x 1 мл	
	Контроль качества, умеренно выраженная патология	3 x 1 мл	
	Контроль качества, высокая патология	3 x 1 мл	

Каждый набор содержит инструкцию по применению.
Паспорт с референсными значениями (допустимых/контрольных пределов).

Каждый флакон содержит 1.0 мл лиофилизированной плазмы человека.

Подготовка: Разведите соответствующую контрольную плазму добавлением во флакон 1.0 мл дистиллированной или деионизированной воды. Осторожно перемешайте и оставьте при комнатной температуре в течение 10 минут. Перед использованием флакон с разведенной плазмой перевернайте (без встряхивания).

НЕОБХОДИМЫЕ КОМПОНЕНТЫ, НЕ ВКЛЮЧЕННЫЕ В КОМПЛЕКТ ПОСТАВКИ

Контрольные плазмы могут быть использованы с анализаторами, имеющими различный метод детекции (механический, оптический и т.д.) в сочетании с реагентами различных производителей.

ХРАНЕНИЕ, СРОК ГОДНОСТИ И УСТОЙЧИВОСТЬ

Новокрытые флаконы с лиофилизированной плазмой хранятся до истечения срока годности в условиях, указанных на этикетке. Разведенная контрольная плазма в закрытом флаконе может храниться при °2 —°8°C или 4 недель при -20°C в случае мгновенной заморозки, в течение 8 часов.

ОТБОР И ПОДГОТОВКА ОБРАЗЦОВ

Не относится.

ПРОЦЕДУРА

Каждый образец контрольной плазмы должен анализироваться так же, как образец плазмы больного, в соответствии с инструкциями к используемому реагенту и прибору.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

«Контроль качества, норма», должен показывать значения в пределах нормального диапазона используемого в лаборатории для ПВ, АПТВ и определения концентрации фибриногена. «Контроль качества, умеренно выраженная патология» и «Контроль качества, высокая патология», были стандартизированы, таким образом, чтобы показывать соответственно умеренно или выраженное увеличение АПТВ и ПВ. Номер партии и допустимые/контрольные пределы для различных коагулометров поставляются с каждым набором контролей.

ОГРАНИЧЕНИЯ

Референсные значения могут варьировать между лабораториями в зависимости от используемых реагентов, методов, коагулометров и других факторов[1,2,3]. По этой причине каждая лаборатория должна установить свои собственные нормативные параметры метода.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными.

НОРМАЛЬНЫЕ ПОКАЗАТЕЛИ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и коагулометров. По этой причине каждая лаборатория должна установить свои собственные значения.

ЭКСПЛУАТАЦИОННЫЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие ориентировочные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики.
При использовании оптико-механического коагулометра и реагентов Хелена были определены следующие коэффициенты вариации (CV):

Воспроизводимость

		в пределах аналитической серии	
Контрольная плазма	***Кол-во образцов***	***CV (%) АПТВ***	***CV (%) ПВ***
Контроль качества, норма	5	2.83	1.01
Контроль качества, умеренно выраженная патология	5	2.76	1.71
Контроль качества, высокая патология	5	1.72	1.03

ЛИТЕРАТУРА

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology*, 37:559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, 55:561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP*, 59:231-235.

Declaration of Conformity

HL-7-0136DC DOI 2015/07 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5185	Calibration Plasma	55995

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 28 Jul 2015

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Declaration of Conformity

HL-7- 0640DC DOI 2015/07 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5504R	Calibration Plasma	55995

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 30 Jul 2015

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SAFETY DECLARATION

Product Description	**Calibration Plasma**
Product Code	**5504R**

The product as received is an IVD kit containing the following materials:

Product Code	Product Description
HL-3-1435SA	PT Calibrant 1 1mL
HL-3-1436SA	PT Calibrant 2 1mL
HL-3-1437SA	PT Calibrant 3 1mL
HL-3-1438SA	PT Calibrant 4 1mL

Each material has been assessed for the chemicals used in its manufacture and has been found to contain **either** no hazardous substances **or** contain them at concentrations or quantities less than those requiring classification under EU regulation 453/2010 or EU regulation 1272/2008.

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Calibration Plasma
Istruzioni per l'uso

it

SCOPO PREVISTO

Il kit Calibration Plasma è concepito per l'uso come materiale di calibrazione.

Il Calibration Plasma può essere utilizzato come plasma di riferimento per il dosaggio dei fattori II, V, VII, VIII, IX, X[1], XI e XII[2], del fibrinogeno[3], del fattore di von Willebrand, della proteina C o della proteina S (totale e libera) antigeniche e funzionali, nonché per i dosaggi cromogenici, compresi l'antitrombina III, la proteina C, il fattore VIII e il plasminogeno. Il Calibration Plasma viene utilizzato nei dosaggi dei fattori e in altri test seguendo la stessa procedura adottata per un pool di plasma fresco. I valori dei fattori II, VII, VIII, IX e X e i valori cromogenici del fattore VIII, dell'AT-III e della proteina C sono riconducibili agli standard dell'Organizzazione Mondiale della Sanità, a garanzia della massima affidabilità dei valori dichiarati[4]. Il plasma di riferimento deve essere utilizzato per valutare i fattori interni adottati nel sistema di ogni singolo laboratorio. Il plasma di riferimento non deve essere utilizzato per determinare i range normali, in quanto i valori normali variano da una popolazione all'altra.

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica *in vitro* - NON INGERIRE. Indossare un'adeguata attrezzatura protettiva personale durante la manipolazione di tutti i componenti del kit. Per conoscere i relativi simboli precauzionali e di pericolo, laddove pertinenti, fare riferimento alla dichiarazione di sicurezza del prodotto. Smaltire i componenti conformemente alle normative locali vigenti.

I prodotti ematici sono stati sottoposti a screening e trovati negativi (salvo diversa indicazione sulla confezione del kit o sulla fiala) per la presenza di:
Antigene dell'epatite B (HbsAg)
Anticorpo HIV 1
Anticorpo HIV 2
Anticorpo HCV
Questi prodotti devono tuttavia essere manipolati con le stesse misure precauzionali adottate per un campione paziente umano.

COMPOSIZIONE

Componente	Contiene	Descrizione	Preparazione
Calibration Plasma	10 x 1 mL	Il Calibration Plasma viene preparato utilizzando un pool congelato di plasma citrato proveniente da donatori sani e quindi viene tamponato e liofilizzato, per garantire la stabilità di tutti i costituenti plasmatici[5].	Ricostituire con 1,0 mL di acqua distillata o deionizzata. Agitare delicatamente. Attendere 20 minuti per consentire al prodotto di sciogliersi completamente.

Ogni kit contiene un'istruzioni per l'uso.
Ogni kit contiene un inserto recante i valori di riferimento specifici per il lotto.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

Il Calibration Plasma può essere utilizzato durante l'esecuzione di test su qualsiasi strumento di coagulazione meccanico o foto-ottico in combinazione con tutti i reagenti idonei disponibili in commercio.

CONSERVAZIONE, VITA UTILE E STABILITÀ

I flaconi non aperti sono stabili fino alla data di scadenza indicata se conservati nelle condizioni riportate sull'flacone o sull'etichetta del kit. I valori relativi al fattore VIII, al fattore di von Willebrand e al cofattore ristocetina sono stabili per 2 ore a °2 –°8°C. Tutti gli altri fattori sono stabili per 4 ore a °2 –°8°C. Il Calibration Plasma non ricostituito deve apparire come un tappo asciutto di colore giallo pallido. Qualora si osservassero condizioni insolite, si raccomanda al cliente di notificarle a Helena Biosciences Europe prima dell'uso.

RACCOLTA E PREPARAZIONE DEI CAMPIONI

Non applicabile.

PROCEDURA

Fare riferimento al manuale utente dello strumento appropriato per istruzioni dettagliate oppure contattare Helena Biosciences Europa per le note applicative specifiche dello strumento.

INTERPRETAZIONE DEI RISULTATI

Quando si utilizza il Calibration Plasma per delineare la curva standard di laboratorio, le percentuali di attività determinate per i vari fattori di coagulazione devono essere ricavate dalla colonna "Valore di riferimento". Assicurarsi che il numero di lotto stampato sul foglio del dosaggio corrisponda a quello riportato sul flacone di Calibration Plasma da utilizzare.

LIMITAZIONI

I risultati ottenuti con il Calibration Plasma dipendono da innumerevoli fattori, strettamente legati alla strumentazione, ai tipi di reagenti, a substrati carenti e alle variazioni dovute ai singoli laboratori[6,7,8]. Ogni laboratorio dovrà definire un range di previsione per il sistema strumento-reagente specificamente utilizzato.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anormali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi.

Helena Biosciences Europe mette a disposizione i seguenti controlli utilizzabili con questo prodotto:
REF 5301 Specialty Assayed Control N
REF 5302 Specialty Assayed Control A

VALORI DI RIFERIMENTO

I valori di riferimento possono variare da un laboratorio all'altro in funzione delle tecniche e dei sistemi in uso. Per tale motivo ciascun laboratorio dovrà elaborare un proprio range normale.

CARATTERISTICHE PRESTAZIONALI

Le seguenti caratteristiche prestazionali sono state determinate da Helena Biosciences Europe e dai propri rappresentanti con l'utilizzo di uno strumento di coagulazione opto-meccanico.

Riproducibilità
Precisione tra i lotti

Parametro	*n*	*Media*	*CV (%)*
Fibrinogeno (g/L)	5	3.0	3.6
Fattore IX (%)	5	124.7	1.9
Proteina S (%)	5	98.5	2.8

BIBLIOGRAFIA

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, *AJCP*, **64:** 817-819.
2. Hardisty RM *et al.* (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229.
3. Morse EE *et al.* (1971) Automated Fibrinogen Determination, *AJCP*, **55:**671-676.
4. Elodi S *et al* (1978) Some Sources of Error in the One-Stage Assay of Factor VIII, *Haemostasis*, **7:**1-9.
5. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasma, *Thrombosis et Diathesis Haemorrhagica*, **19:**423.
6. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay. *British Journal of Haematology*, **37:**559-568.
7. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, **56:**561-564.
8. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP*, **59:**231-235.

Calibration Plasma
Instrucciones de uso

es

USO PREVISTO

El uso previsto del kit Calibration Plasma es como material de calibración.

El Calibration Plasma puede usarse como plasma de referencia cuando se valoran los factores II, V, VII, VIII, IX, X[1], XI, XII[2], fibrinógeno[3], factor de von Willebrand, proteína C antigénica y funcional y proteína S (total y libre), así como las valoraciones cromógenas como antitrombina III, proteína C, factor VIII y plasminógeno. Calibration Plasma se usa en valoraciones de factores y en otras pruebas de la misma forma que una reserva de plasma fresco. Los valores de los factores II, VII, VIII, IX y X y los valores cromogénicos de factor VIII, AT-III y proteína C se pueden referenciar a los estándares de Organización Mundial de la Salud para asegurar la máxima credibilidad en los valores indicados[4]. Debe usarse el plasma de referencia para calibrar factores internos en el sistema de cada laboratorio. No debe usarse el plasma de referencia para determinar los intervalos normales, porque los normales varían de una población a otra.

ADVERTENCIAS Y PRECAUCIONES

Los reactivos que contiene este kit son sólo para uso de diagnóstico *in vitro*: NO INGERIR. Lleve el equipo de protección personal adecuado cuando utilice todos los componentes del kit. Consulte la declaración de seguridad del producto para saber más sobre las indicaciones adecuadas de advertencia y riesgo. Desechar los componentes de conformidad con las normativas locales.

La sangre se ha sometido a pruebas que han resultado negativas (a menos que se indique lo contrario en la caja del kit o en el vial) de la presencia de:
Antígeno de la hepatitis B (HbsAg)
Anticuerpos del VIH 1
Anticuerpos del VIH 2
Anticuerpos del VHC
Sin embargo, deben manipularse con las mismas precauciones que una muestra de un paciente.

COMPOSICIÓN

Componente	Contiene	Descripción	Preparación
Calibration Plasma	10 x 1 mL	El Calibration Plasma se elabora a partir de una reserva congelada de plasma citratado de donantes sanos y está tamponado y liofilizado para asegurar la estabilidad de todos los constituyentes del plasma[5].	Reconstituya con 1,0 mL de agua destilada o desionizada. Agite suavemente. Espere 20 minutos para que el producto se disuelva completamente.

Cada kit contiene instrucciones de uso.
Cada kit contiene valores de referencia específicos insertados del lote.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

El Calibration Plasma puede usarse cuando se realizan pruebas con cualquier instrumento de coagulación mecánica o foto-óptica junto con todos los reactivos adecuados, comerciales.

ALMACENAMIENTO, CADUCIDAD Y ESTABILIDAD

Los viales no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en la etiqueta del vial o el kit. Los valores para el factor VIII, el factor de von Willebrand factor y el cofactor de ristocetina son estables durante 2 horas a °2 –°8°C. Todos los demás factores son estables durante 4 horas a °2 –°8°C. El Calibration Plasma no reconstituido debe aparecer como un tapón seco, de color amarillo claro. Si se nota alguna condición inusual, el usuario debe notificárselo a Helena Biosciences Europe antes de usarlo.

RECOGIDA Y PREPARACIÓN DE LAS MUESTRAS

No aplicable.

PROCEDIMIENTO

Consulte el manual del usuario del instrumento adecuado para instrucciones detalladas o póngase en contacto con Helena Biosciences Europe para notas de aplicación específicas del instrumento.

INTERPRETACIÓN DE LOS RESULTADOS

Las actividades porcentuales valoradas de los diversos factores de coagulación deben tomarse de la columna "Valor de Referencia" cuando se usa el Calibration Plasma para determinar las curvas estándar de laboratorio. Compruebe que el número de lote impreso en esta hoja de valoración es el mismo que en el vial de Calibration Plasma a usar.

LIMITACIONES

Los resultados obtenidos con Calibration Plasma dependen de varios factores fuertemente asociados a la instrumentación, los tipos de reactivos, sustratos deficientes y variaciones entre laboratorios[6,7,8]. Cada laboratorio debe establecer un intervalo esperado para el sistema instrumento-reactivo concreto.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los plasmas de control normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos.

Helena Biosciences Europe suministra los siguientes controles disponibles para usar con este producto:
REF 5301 Specialty Assayed Control N
REF 5302 Specialty Assayed Control A

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y los sistemas usados. Por esta razón, cada laboratorio debe establecer su propio intervalo normal.

CARACTERÍSTICAS FUNCIONALES

Las siguientes características de rendimiento han sido determinadas por Helena Biosciences Europe o sus representantes usando un instrumento de coagulación opto-mecánico.

Reproductibilidad
Precisión interlote

Parámetro	*n*	*Media*	*CV (%)*
Fibrinógeno (g/L)	5	3.0	3.6
Factor IX (%)	5	124.7	1.9
Proteína S (%)	5	98.5	2.8

BIBLIOGRAFÍA

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, *AJCP*, **64:** 817-819.
2. Hardisty RM *et al.* (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229.
3. Morse EE *et al.* (1971) Automated Fibrinogen Determination, *AJCP*, **55:**671-676.
4. Elodi S *et al* (1978) Some Sources of Error in the One-Stage Assay of Factor VIII, *Haemostasis*, **7:**1-9.
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6. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay. *British Journal of Haematology*, **37:**559-568.
7. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, **56:**561-564.
8. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP*, **59:**231-235.

УНИВЕРСАЛЬНЫЙ КАЛИБРАТОР
инструкция

ru

НАЗНАЧЕНИЕ

Комплект «Универсальный калибратор» предназначен для использования в качестве материала для калибровки.

«Универсальный калибратор» может использоваться как референсная плазма, для определения факторов II, V, VII, VIII, IX, X[1], XI, XII[2], фибриногена[3], фактора Виллебрандта, антигена и функциональной активности Протеина С и Протеина S (общего и свободного), так же «Универсальный калибратор» можно использовать и для хромогенных тестов, включая Антитромбин III, Протеин С, фактор VIII и Плазминоген. «Универсальный калибратор» используется при калибровке тестов для определения II, VII, VIII, IX и X факторов, а также при калибровке хромогенных тестов: VIII фактора, Антитромбина - III и Протеина С. Уровень значений сопоставим с рекомендациями ВОЗ[4]. Использование референсной плазмы нивелирует влияние внешних факторов на результаты анализа. Референсная плазма не должна использоваться для определения нормального диапазона значений, так как значения нормы варьируют в зависимости от биологических особенностей популяции практически здоровых людей.

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Содержащиеся в данном наборе реагенты предназначены только для *in vitro* диагностики– НЕ ПРИНИМАТЬ ВНУТРЬ! При работе со всеми компонентами набора использовать соответствующие средства индивидуальной защиты. В случае необходимости см. свидетельство о безопасности изделия для ознакомления с соответствующими описаниями опасного воздействия и сведениями о мерах предосторожности. Удаление компонентов и отходы производите в соответствии с местными правилами.

Препараты крови были подвергнуты скринингу и показали отрицательный результат (если на коробке, в которую упакован комплект или на пробирке не указано иное) на:
Антиген к гепатиту В (HbsAg)
Антитела к ВИЧ 1
Антитела к ВИЧ 2
Антитела к вирусу гепатита С (HCV)
Тем не менее с ними следует обращаться, соблюдая те же меры предосторожности, что и при обращении с образцом, полученным от человека.

СОСТАВ

Компоненты	Состав набора	Описание	Приготовление реагентов
Плазма калибратор	10 x 1 мл	приготовлен из объединенной цитратной плазмы, полученной от практически здоровых доноров. Плазма заморожена и лиофилизирована, чтобы гарантировать стабильность всех плазменных элементов[5].	Разведите соответствующую контрольную плазму добавлением во флакон 1.0 мл дистиллированной или деионизированной воды. Осторожно перемешайте и оставьте при комнатной температуре в течение 20 минут. Перед использованием флакон с разведенной плазмой переворачивайте (без встряхивания).

Каждый набор содержит инструкцию по применению.
Паспорт с референсными значениями.

НЕОБХОДИМЫЕ КОМПОНЕНТЫ, НЕ ВКЛЮЧЕННЫЕ В КОМПЛЕКТ ПОСТАВКИ

Контрольные плазмы могут быть использованы с анализаторами, имеющими различный метод детекции (механический, оптический и т.д.) в сочетании с реагентами различных производителей.

ХРАНЕНИЕ, СРОК ГОДНОСТИ И УСТОЙЧИВОСТЬ

Неоткрытые флаконы с лиофилизированной плазмой хранятся до истечения срока годности в условиях, указанных на этикетке. Разведенная плазма в закрытом флаконе может храниться при °2 –°8°C в течение 4 часов. Значения для VIII фактора, фактор Виллебрандта и КоФактор ристоцетина устойчивы в течение 2 часов при °2 –°8°C. Неразведенный калибратор должен выглядеть, как светло-желтый сухой плотный лиофилизат. При появлении необычных признаков продукта, до использования обратитесь в компанию Хелена.

ОТБОР И ПОДГОТОВКА ОБРАЗЦОВ

Не относится.

ПРОЦЕДУРА

«Универсальный калибратор» может использоваться, для выполнения тестов на любом механическом или оптическом коагулометре в наборе с любыми подходящими реактивами. Адаптации реагентов к различным приборам доступны по запросу у официальных дистрибьюторов и компании Хелена.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

Значение процента активности различных факторов свертывания должна быть взята из колонки "референсные значения", когда вы используете «Универсальный калибратор», чтобы определить стандартные лабораторные кривые. Убедитесь, что номер партии, напечатанный в паспорте, совпадает с номером указанным на используемом Вами флаконе калибратора.

ОГРАНИЧЕНИЯ

Референсные значения могут варьировать между лабораториями в зависимости от используемых реагентов, методов, коагулометров и других факторов[6,7,8]. По этой причине каждая лаборатория должна установить свои собственные нормативные параметры метода.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными.
Компания Хелена рекомендует следующие контрольные материалы:
Кат. № 5301 Контроль качества специальные тесты, норма
Кат. № 5302 Контроль качества специальные тесты, патология

НОРМАЛЬНЫЕ ПОКАЗАТЕЛИ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и коагулометров. По этой причине каждая лаборатория должна установить свои собственные значения.

ЭКСПЛУАТАЦИОННЫЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие ориентировочные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики.
При использовании оптико-механического коагулометра и реагентов Хелена были определены следующие коэффициенты вариации (CV):

Воспроизводимость
в пределах аналитической серии

Тест	*n*	*Среднее*	*CV (%)*
Фибриноген (г/л)	5	3.0	3.6
Фактор IX (%)	5	124.7	1.9
Протеин S (%)	5	98.5	2.8

ЛИТЕРАТУРА

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, *AJCP*, **64:** 817-819.
2. Hardisty RM *et al.* (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229.
3. Morse EE *et al.* (1971) Automated Fibrinogen Determination, *AJCP*, **55:**671-676.
4. Elodi S *et al* (1978) Some Sources of Error in the One-Stage Assay of Factor VIII, *Haemostasis*, **7:**1-9.
5. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasma, *Thrombosis et Diathesis Haemorrhagica*, **19:**423.
6. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay. *British Journal of Haematology*, **37:**559-568.
7. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, **56:**561-564.
8. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP*, **59:**231-235.

en

INTENDED PURPOSE

The Calibration Plasma set is intended for use with Thromboplastin LI for the following purposes:

- Establish a %PT Calibration Curve.
- Establish an INR Reference Curve for the direct INR determination of a patient sample.
- Establish specific ISI and MNPT values for the system, reagent and instrument, used by the laboratory.

WARNINGS AND PRECAUTIONS

The reagents contained within this kit are intended for in vitro diagnostic use only. **DO NOT INGEST.** Wear gloves when handling all kit components. Plasma products have been screened and found negative for the presence of Hepatitis B surface antigen (HbsAg), HIV 1 and 2 antibody and HCV antibody; however they should be regarded as potentially infectious and handled and disposed with appropriate care in compliance with local regulation.

COMPOSITION

The Calibration Plasma set contains 4 PT Calibrants for standardising the PT test. The plasmas are prepared from pooled normal human plasmas. PT Calibrant 1 simulates normal human plasmas, PT Calibrant 2, PT Calibrant 3 and PT Calibrant 4 simulate a range of plasma pathologies and are prepared through the absorption of clotting factors. The assigned values for each of the plasma are indicated on the insert sheet expressed as %PT and INR, the values are intended for use with Thromboplastin LI and are instrument/instrument series specific.

- 1 × 1 mL – PT Calibrant 1
- 1 × 1 mL – PT Calibrant 2
- 1 × 1 mL – PT Calibrant 3
- 1 × 1 mL – PT Calibrant 4

PREPARATION

Reconstitute with 1.0 mL of distilled or deionized water, allow the vial to stand for 15 minutes and mix gently before use to allow complete dissolution. **DO NOT SHAKE.**

STORAGE AND SHELF-LIFE

Unopened vials should be stored at 2-8°C and are stable until the expiration data stated on the labels. Reconstituted plasma must be used within 1 hour.

TEST PROCEDURE

The reconstituted plasmas should be treated in the same way as patient samples following normal instrument and thromboplastin protocols.

INTERPRETATION OF THE RESULTS

Establishing a %PT Calibration Curve

Determine the coagulation times of each of the 4 PT Calibrants in duplicate or triplicate. Plot the mean value obtained for each calibration plasma on double log paper (x-axis = %PT value; y-axis = Coagulation time in seconds). Join the points (point – point) and determine the PT coagulation time of the patient plasma and directly read from this reference line the corresponding %PT value of patient plasma.

Establishing an INR Reference Curve for the direct INR determination of a patient sample

Determine the coagulation times of each of the 4 PT Calibrants in duplicate or triplicate. Plot the mean value obtained for each calibration plasma on double log paper (x-axis = INR value; y-axis = Coagulation time in seconds). Join the points by fitting the best possible straight line through these points. Determine the PT coagulation time of the patient plasma and directly read from this reference line the corresponding INR value of patient plasma.

Establishing Laboratory Specific ISI and MNPT

Determine the coagulation times of each of the 4 PT Calibrants in duplicate or triplicate and calculate the mean value for each of the plasma. A linear relationship exists between the Log INR value (x-axis) and Log PT (sec; y-axis), expressed by the equation:

$$\text{Log PT (sec)} = [\text{slope} \times \text{Log (INR)}] + \text{intercept}$$

From this equation the laboratory specific ISI and MNPT can be calculated in the following way:

$$\text{ISI} = \text{slope}$$
$$\text{MNPT} = 10^{\text{intercept}}$$

The PT Calibrants can be used on automated equipment. On Sysmex CA series and Sysmex CS series the assigned values of PT Calibrants can be entered as "Manual Dilution" in the "Standard Curve" sub-menu. Carefully read and follow the operating procedures for the specific instrument.

QUALITY CONTROL

Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid.
Helena BioSciences supply the following controls available for use with this product:

REF 5186 Routine Control N
REF 5187 Routine Control A
REF 5183 Routine Control SA
REF 5301 SAC N
REF 5302 SAC A

REFERENCE VALUES

Reference values can vary between laboratories depending on the techniques and systems in use.

LIMITATION OF THE TEST

A new calibration is required for each batch of thromboplastin and for each instrument used. Recalibration is also recommended if software changes are introduced or following a major service or repair of the instrument.

The INR and %PT values of calibration plasmas supplied with this kit are lot specific.

helena Biosciences Europe

Calibration Plasma

Instructions for use

REF 5504R

Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
Tel. +44 (0)191 482 8440
Fax +44 (0)191 482 8442
Email info@helena-biosciences.com
www.helena-biosciences.com

CE

HL-2-2658P 2012/11 (1)

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 декабря 2015 года № ФСР 2011/11306

На медицинское изделие
Краситель Азур-Эозин по Романовскому (МиниМед-Р)
по ТУ 9398-003-29508133-2011

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Место производства медицинского изделия
241520, Брянская область. Брянский район, с. Супонево, пер. Комсомольский, д. 7, корп. 2-а

Номер регистрационного досье **№ РД-9275/51846 от 18.11.2015**

Вид медицинского изделия **232730**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 07 декабря 2015 года № 9111
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

0015715

АНАЛИТИЧЕСКИЙ ПАСПОРТ

Набор реактивов для
лабораторной диагностики
скрытой крови
ОКП 93 9816

СЕРИЯ 0719

Дата изготовления ИЮЛ 2019

Изготовитель НИИ ИТиМ, Санкт-Петербург

№Показатель	Требования по ТУ	Результаты анализа
1.Внешний вид 1.11. Реактив А амидопирин 1.12. Реактив СА Соляноксилый анилин	Порошок белого цвета Порошок белого (от серого до светло-зелёного) цвета	СООТВЕТСТВУЕТ СООТВЕТСТВУЕТ
2.Технические характеристики 2.1.Чувствительность Азопирамовой пробы из данных реагентов Положительная реакция при разведении крови не менее	1:50000	СООТВЕТСТВУЕТ

Заключение: требования ТУ СООТВЕТСТВУЕТ

Начальник ОТК Гаврилов К.Е.

СЕРТИФИКАТ КАЧЕСТВА

Настоящим удостоверяется , что товар, идентифицированный как сухие компоненты реактива для определения скрытой крови Азопирам лабораторная диагностика
код:382200000 ТНВЭД ОКПО 52125484
Страна происхождения : Россия
Изготовитель: НИИ ИТи М
Дата изготовления: ИЮЛ 2019
Годен до: ИЮЛ 2020
№ партии: 0719
Соответствует требованиям:
1 ГОСТ 53122-78
2.Государственной Фармакопее СССР,ст.45
3. Методическим указаниям МЗ СССР 28-6/13 от 26,05,1988г.

Подпись ответственного лица

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

CTK Biotech, Inc.
13855 Stowe Dr.
Poway
California
92064
USA

Holds Certificate No: **FM 517416**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Research, design and development, manufacturing and distribution of in vitro diagnostic reagents, controls, test kits and instruments for use in the areas of Autoimmune / Allergy, Cardiac Markers, Fertility, Infectious Diseases, Endocrinology, Oncology, and Veterinary.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2007-07-26
Latest Revision Date: 2019-05-10

Effective Date: 2019-05-16
Expiry Date: 2022-05-15

...making excellence a habit.™

Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

CTK Biotech, Inc.
13855 Stowe Dr.
Poway, CA 92064
USA

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated Nov 26, 2019

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

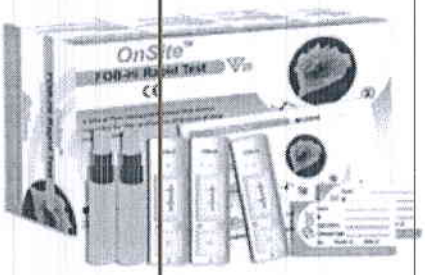
2019-11-26

Joy Grimm
Senior Consultant
MDSS GmbH

FOB-Hi Rapid Test CE

The OnSite FOB-Hi Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of fecal occult blood in human fecal specimens in laboratories or physician offices.

It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the detection of bleeding caused by a number of gastrointestinal disorders, e.g. diverticulitis, colitis, polyps, and colorectal cancer.



- Designed to specifically detect low levels of fecal occult blood, hHB ≥ 25 ng/mL
- Higher accuracy, sensitivity and specificity than the Guaiac Test
- No dietary restrictions
- Clear, easy-to-interpret result
- Individually sealed foil pouches containing:
  - One cassette test device
  - One desiccant
- Stool collection devices, each containing 2 mL of extraction buffer (REF SB-R2011)
- Patient ID stickers
- One package insert (instruction for use)

OnSite™ FOB-Hi Rapid Test

REF R2011C CE

INTENDED USE

The *OnSite* FOB-Hi Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of fecal occult blood in human fecal specimens in laboratories or physician offices. It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the detection of bleeding caused by a number of gastrointestinal disorders, e.g. diverticulitis, colitis, polyps, and colorectal cancer.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

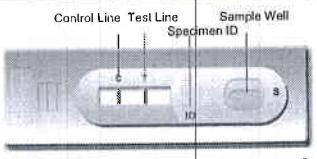
The American Cancer Society and Centers for Disease Control recommend an occult blood feces test annually after age 50 to aid in the early detection of colorectal cancer[1].Two types of FOB tests are commercially available: guaiac dye tests and immunochemical tests (iFOBT).

The guaiac tests are widely used but lack accuracy. The guaiac dye is a naturally occurring phenolic compound that can be oxidized to quinone by hydrogen peroxidase activity of human hemoglobin (hHb) resulting in a detectable color change. The sensitivity and specificity of guaiac tests are much lower than those of immunochemical assays. The low accuracy of the guaiac tests is related to dietary peroxidases, including hemoglobin from meat and uncooked fruits and vegetables. Non-cancerous gastrointestinal tract bleeding and iron intake may also cause false positive results with guaiac tests[2].

Immunochemical tests are highly accurate for the detection of hHb compared to the guaiac method. The results of immunochemical FOB tests (iFOBT) are not affected by dietary peroxidases, animal blood or ascorbic acid. A Japanese study demonstrated that iFOB screening tests reduced mortality of colorectal cancer by 60%[3].

The *OnSite* FOB-Hi Rapid Test is an iFOBT designed to specifically detect low levels of human fecal occult blood. It can be performed within 10 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE



The *OnSite* FOB-Hi Rapid Test is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-hHb antibody conjugated with colloid gold (anti-hHb conjugates) and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with another monoclonal anti-hHb antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. hHb, if present in the specimen at or higher than 25 ng/mL, will bind to the anti-hHb conjugates. The immunocomplex is then captured by the pre-coated reagent forming a burgundy colored T line, indicating a FOB positive test result.

Absence of the T line suggests a negative result. Each test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control line antibodies regardless of the color development on the T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette test device
   b. One desiccant
2. Stool collection devices, each containing 2 mL of sample extraction buffer (REF SB-R2011)
3. Patient ID stickers
4. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND AVAILABLE FOR PURCHASE

1. *Positivia* FOB Rapid Test Control Kit (Cat # C2011) contains positive control and negative control.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. A container to hold fecal specimen

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the instructions may give inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use any kit components beyond their stated expiration date.
4. Do not use the components in any other type of test kit as a substitute for the components in this kit.
5. Bring all reagents to room temperature (15-30°C) before use.
6. **Do not scoop fecal specimen as this may lead to excess fecal specimen that may block the sample well and result in an invalid test result.**
7. **Do not use specimens for testing if blood is visible.**
8. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
9. Users of this test should follow the US CDC Universal Precautions for bio-safety.
10. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
12. The testing results should be read 10 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside 10 minutes should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. The positive and negative controls should be kept at 2-8°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature above 30°C.

PATIENT PREPARATION

1. Specimens should not be collected from patients with the following conditions which may interfere with the test results:
   - Menstrual bleeding
   - Bleeding hemorrhoids
   - Constipating bleeding
   - Urinary bleeding
2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, and produce positive reactions. On the advice of a physician, these medicines may be temporarily discontinued for 7 days prior to and during the test period.

SPECIMEN COLLECTION AND HANDLING

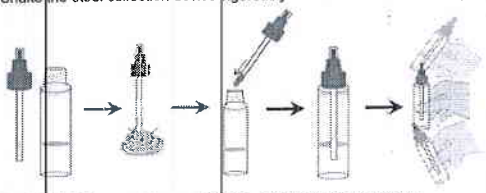
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Step 1: Collect a random sample of feces in a clean, dry receptacle.

Step 2: Label the stool collection device with the specimen's ID number (patient ID sticker). Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool specimen in at least five different sites. ***Do not scoop stool specimen. Ensure that stool specimen is only in the grooves of the collection stick. Excess stool specimen may lead to an invalid test result.***

Step 3: Replace the collection stick in the tube and tighten securely to close the sample extraction tube.

Step 4: Shake the stool collection device vigorously to extract the hHb in the specimen.



The specimen is now ready for testing, transportation or storage.

Note: It is recommended to test the specimen immediately after extraction. If not tested immediately, the extracted specimen may be stored at room temperature (20-37°C) for up to 10 days or at 2-8°C for up to 21 days. For longer storage, the extracted specimen may be frozen at -20°C. Avoid multiple freeze-thaw cycles.

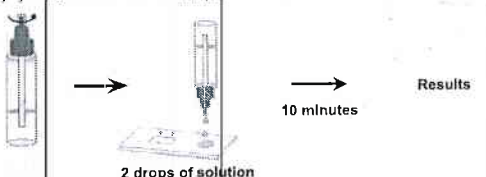
TEST PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Shake the stool collection device vigorously to ensure an homogenous liquid suspension.

Step 4: Hold the stool collection device vertically. Twist off the tip. Dispense 2 drops (70-90 µL) of the solution into the sample well of the cassette. Do not overload samples.



Step 5: Set up timer.

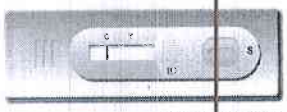
Step 6: Results can be read at 10 minutes. Positive results can be visible in as short as 1 minute. Negative results must be confirmed at the end of the 10 minutes only. ***However, any results interpreted outside 10 minutes should be considered invalid and must be repeated. Discard used device after interpreting the result following local laws governing the disposal of device.***

QUALITY CONTROL

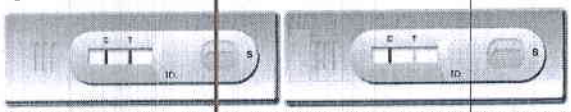
1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding sample. If the C line does not develop, review the whole procedure and repeat test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the test kit, prior to performing testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of test kits is used.
   d. The temperature during storage of the kit falls outside of 2-30°C.
   e. The temperature of the test area falls outside of 15-30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULTS

1. **NEGATIVE RESULT:** If only the C line develops, the test indicates that the concentration of hHb in the sample is below 25 ng/mL in buffer. The result is negative or non-reactive.

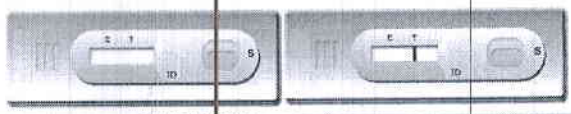


2. **POSITIVE RESULT:** In addition to the presence of the C line, if the T line develops, the test indicates that the concentration of hHb in the sample is equal to or higher than 25 ng/mL in buffer. The result is FOB-HI positive or reactive.



Specimens with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

3. **INVALID:** If no C line develops, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new device. ***If caused by an excess amount of fecal specimen collected, collect a new specimen and retest.***



PERFORMANCE CHARACTERISTICS

1. **Sensitivity**

   The analytical sensitivity of the test is 25 ng/mL hHb in buffer or 3.5 µg/g hHb in feces.

2. **Specificity**

   The *OnSite* FOB-Hi Rapid Test is specific to human hemoglobin. The following substances, when spiked in both positive and negative specimens, did not interfere with the test results.

1. Chicken Hemoglobin	2 mg/mL	6. Horse Hemoglobin	2 mg/mL
2. Turkey Hemoglobin	2 mg/mL	7. Sheep Hemoglobin	2 mg/mL
3. Pig Hemoglobin	2 mg/mL	8. Fish Hemoglobin	2 mg/mL
4. Beef Hemoglobin	2 mg/mL	9. Rabbit Hemoglobin	2 mg/mL
5. Goat Hemoglobin	2 mg/mL		

3. **Dose Hook Effect**

   The *OnSite* FOB-Hi Rapid Test cassettes do not show any hook effect or prozone effect up to the concentration of 4 mg/mL hHb in buffer.

4. **Reproducibility**

   Known positive specimens were tested in multiple assays and identically positive results were observed. Similarly, known negative specimens produced negative results when tested in multiple assay.

5. **Clinical Performance**

   A total of 135 specimens were collected and tested by the *OnSite* FOB-Hi Rapid Test and by a leading commercial FOB rapid test. Comparison for all specimens is shown in the following table:

	OnSite FOB-HI Rapid Test		
Reference Test	Positive	Negative	Total
Positive	46	2	48
Negative	1	86	87
Total	47	88	135

Relative Sensitivity: 95.8%, Relative Specificity: 98.8%, Overall Agreement: 97.8%

6. **Interference**

   Common substances (such as pain and fever medication, blood components) may affect the performance of the *OnSite* FOB-Hi Rapid Test. This was studied by spiking these substances into negative serum and negative serum samples spiked with two levels of FOB standard controls (negative and positive). The results demonstrate, at the concentrations tested, the substances studied do not affect the performance of the *OnSite* FOB-Hi Rapid Test.

List of potentially interfering substances and concentrations tested:

1. Ascorbic acid	20 mg/dL	4. Dietary iron (Fe^{2+}/Fe^{3+})	5 mg/dL
2. Bilirubin	100 mg/dL	5. Glucose	2,000 mg/dL
3. Caffeine	40 mg/dL	6. Horseradish Peroxidase	20 mg/mL

LIMITATIONS OF THE TEST

1. The Test Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of occult blood in feces. Failure to follow the procedure may give inaccurate results.
2. The *OnSite* FOB-Hi Rapid Test is to aid in diagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.
3. A negative or non-reactive result can be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease. A negative or non-reactive result can also be obtained if the quantity of occult blood present in the specimen is below the detection limit of the assay.
4. The *OnSite* FOB-Hi Rapid Test has not been validated for testing of patients with hemaglobinopathies.
5. Specimens containing visible blood may produce negative results due to the hook effect.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. America Cancer Society, Inc. Cancer Reference Information: Can Colon and Rectum Cancer be Found Early? (Online) Available: http://www.cancer.org.
2. Allison JB, Takawa IS, Ransom LJ, Adrian AL. A comparison of fecal occult blood tests for colorectal –cancer screening. N. Eng. J. Med. 1996; 334:155-159.
3. Saito H. Screening for colorectal cancer by immunochemical fecal occult blood testing (Review). Jpn J. Cancer Res 1996; 87:1011-1024.

Index of CE Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ_N	Tests per kit
2°C 30°C	Store between 2-30°C	EC REP	Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
10110 Mesa Rim Road
San Diego, CA 92121, USA
Tel: 858-457-8698
Fax: 858-535-1739
E-mail: info@ctkbiotech.com

PI-R2011C Rev. E
Date released: 2016-03-14
English Version

For Export Only, Not For Re-sale In the USA

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

LORNE LABORATORIES

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
RPR Carbon kit	044150A 044500A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.

Eddy Velthuis
Technical Director

LORNE LABORATORIES LTD.
GREAT BRITAIN

SYPHILIS SEROLOGY KIT
DIRECTIONS FOR USE

RPR CARBON KIT: For Detection Of Syphilis.

SUMMARY

At one time, syphilis was a major medical disease with a host of different manifestations transmitted primarily through sexual contact. The advent of penicillin in 1943 changed this. The etiologic agent of syphilis is *Treponema pallidum*, a spiral bacterium (spirochete). The spirochete causes some damage to the heart and the liver, releasing some tissue fragments. The patient's immune system produces antibodies, called reagins, against these fragments. There are two different techniques for the detection of syphilis. TPHA tests, which detect antibodies to *Treponemal pallidum*, and non-treponemal serologic tests, which detect Reagin in infected people.

PRINCIPLE

When used by the recommended techniques, the reagent will agglutinate (clump) in the presence of reagin. No agglutination usually indicates the absence of reagin (see **Limitations**).

KIT DESCRIPTION

Lorne RPR Carbon Kit is a non-treponemal serologic test for the detection of syphilis. The RPR Carbon Antigen contains micro particulate carbon, which aids in the microscopic reading of results. All the reagents are supplied at optimum dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMEN COLLECTION

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8°C for 7 days or for up to 3 months at or below –20°C. Specimens must be free from bacterial contamination, fibrin, haemolysis and lipaemia.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. No known tests can guarantee products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.
5. RPR Positive Control: H319 - Causes serious eye irritation. Follow the precautionary statement given in the SDS.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended the RPR Positive and Negative Controls be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. Shake all the reagents well before use to ensure homogeneity.
3. Do not interchange components between different kits.
4. The circles on the agglutination cards should never be touched with fingers, as this may invalidate the test results.
5. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of country where reagents are in use.
6. The user must the determine suitability of the kit for use in other techniques.

KIT COMPONENTS PROVIDED

1) RPR Carbon Antigen (Red Label): Carbon particles coated with a lipid complex (cardiolipin, lecithin and cholesterol) in phosphate buffer 20 mmol/L, pH 7.0 containing a preservative.
2) RPR Positive Control (Red cap): Artificial serum with reagin titer ≥ 1/4.
3) RPR Negative Control (Blue cap): Animal serum containing a preservative
4) Dispensing bottle (1 x 2 ml).
5) Dispensing Needle (x1).
6) Disposable agglutination slides.
7) Plastic stirrers.

MATERIALS AND EQUIPMENT NOT SUPPLIED

a) Pipette capable of accurately delivering 50 µl
b) Mechanical rotating table capable of rotating at 80-100 rpm.
c) 9 g/L saline solution.

QUALITATIVE TECHNIQUE

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the RPR-carbon reagent gently before using. Invert the dropper assembly and press gently to remove air bubbles from the micropipette.
4. Place the micropipette in a vertical position and perpendicular to the slide, and add one drop (20 µL) of this reagent next to the samples to be tested.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample
6. Place the slide on a mechanical rotating table at 80-100 r.p.m. for 8 min. False positive results could appear if the test is read after more than 8 minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Reactive:** Visible agglutination (medium to large clumps) constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
2. **Weak-Reactive:** Weak agglutination (small clumps) around the periphery of the test area constitutes a weak positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
3. **Negative:** No agglutination constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of reagin.

SEMI QUANTITATIVE TECHNIQUE

1. The semi-quantitative test can be performed in the same way as the quantitative technique using dilutions of the serum in 9 g/L saline solution.
2. Make doubling dilutions of specimen as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl
1/16	100 µl 1/8 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Read the test and note the last positive dilution series.

STABILITY OF THE REACTIONS

Slide tests should be interpreted straight after the 8-minute rotating period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. RPR carbon test is non-specific for syphilis. All Reactive samples should be retested with treponemic methods such as TPHA and FTA-Abs to confirm the results.
2. A Non Reactive result by itself does not exclude a diagnosis of syphilis. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
3. False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.
4. Bilirubin (≤ 20 mg/dL), hemoglobin (≤ 10 g/L) and lipids (≤ 10 g/L), do not interfere. Rheumatoid factors (≥ 300 IU/mL), interfere. Other substances may interfere[5].
5. False positive or negative results may also occur due to:
   a) Not expelling air from end of needle
   b) Not maintaining dispensing bottle and needle in a vertical position when dispensing the antigen.
   c) When transferring the specimen from the collecting tube some of the specimen being drawn up in to the teat
   d) Contamination of test materials
   e) Improper storage of test materials or omission of reagents
   f) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques.**
2. Prior to release, each lot of Lorne RPR Syphilis Kit is tested by the **Recommended Techniques** to ensure suitable reactivity.
3. The reagent sensitivity is calibrated against the WHO 1st International Standard for human syphilitic plasma (NIBSC reference number 05/132).
4. **Prozone effect:** No prozone effect was detected up to titers ≥1/128.
5. **Diagnostic sensitivity:** 100%
6. **Diagnostic specificity:** 100 %.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques.**
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. George P. Schimid. Current Opinion in Infectious Diseases 1994; 7: 34-40.
2. Sandra A Larsen et al. Clinical Microbiology Reviews 1995; 8 (1): 1-21.
3. Sandra Larsen et al. A manual of Test for Syphilis American Public Health Association 1990: 1-192.
4. Joseph Earle Moore et al. Gastrointestinal Haemorrhage 1952; 150(5): 467-473.
5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
150 Tests Per Kit	044150A
500 Tests Per Kit	044500A

For the availability of other sizes, please contact:

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire, RG6 4UT
England
Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com

TABLE OF SYMBOLS

LOT	Batch Number	IVD	*In-vitro* Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		

TÜVRheinland®

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60119814 0001

Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products: Products for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60076687 0001

Expiry Date: 2022-05-28

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Notified Body

Effective Date: 2017-05-29

Date: 2017-05-29

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: **HL 60119814 0001**
Report No.: **21265422 001**

Manufacturer: **Macherey-Nagel GmbH & Co. KG**
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products for self-testing:
- Single and multi-parameter disposable test strips for urine analysis
- indicator test strips and papers for measurement of pH in urine

Additional site for warehousing and logistics:

Bahnstr. 120
52355 Düren, Germany

Notified Body

Date: 2017-05-29

Dipl.-Ing. Sven Hoffmann

HBsAg Rapid Test

The OnSite HBsAg Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum or plasma at a level equal to or higher than 1 ng/mL.

Uses human serum or plasma

Can be performed without the use of laboratory equipment

Result in 15 minutes

Individually sealed foil pouches containing:

One cassette device

One desiccant

Plastic droppers

Package insert (instruction for use)

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-А во флаконах по 10 мл с красными крышками

Серия: 096111 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 40

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: А096111 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп B(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп A(III) и O(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы O(I)	Соответствует Соответствует Соответствует
2,1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2,3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы A(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы B(III) 1 : 64 Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп A(II) 1:32 - 1: 64 и B(III) 1 : 64	Соответствует 1:32 - 1: 64 Соответствует 1:64 Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-В во флаконах по 10 мл с синими крышками

Серия: 095810 **Единица:** 100 мл

Изготовлен: 21.10.2019 **Количество единиц** 40

Годен до: 21.10.2021 **Объем серии:** 10000 мл.

Паспорт: В095810 от 21.10.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп B(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп A(III) и O(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы O(I)	Соответствует Соответствует Соответствует
2,1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2,3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы A(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы B(III) 1 : 64 Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп A(II) 1:32 - 1: 64 и B(III) 1 : 64	Соответствует 1:32 - 1: 64 Соответствует 1:64 Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН

ООО "Медиклон"

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ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-АВ

Серия: 098611 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 10

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: АВ098611 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и О(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует Соответствует Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64 Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:32 - 1: 64 Соответствует 1:64 Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35, т\ф (495) 231-2272 (499) 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-D Супер)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D Супер во флаконах по 10 мл с зелеными крышками

Серия: 292711 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 40

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: Дс292711 от 05.11.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(–) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступать в течение 30 сек. после смешивания реагента с D(+) эритроцитами	Соответствует 30 сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32 Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроцитами в микропланшете не ниже 1:256	Соответствует 1:32 1:256

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

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Unit 1 Cutbush Park Industrial Estate
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www.lornelabs.com

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

File No A12241;
ISO 13485:2003, ISO 9001:2008

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LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

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LORNE LABORATORIES LTD.
GREAT BRITAIN

CE

RAPID LATEX KIT
DIRECTIONS FOR USE

ASO Latex Kit: For Detection Of Anti-Streptolysin O (ASO) In Serum.

SUMMARY

In acute streptococcal infections, the toxic immunogenic exoenzyme streptolysin O (ASO) is produced in response to streptolysin O antigens liberated by haemolytic streptococci of groups A, C and G. Information on extent and degree of infection can be obtained by measuring serum ASO levels. Elevated ASO levels have also been found in patients suffering from scarlet fever, acute rheumatoid arthritis, tonsillitis, and other streptococcal infections as well as in healthy carriers.

PRINCIPLE

When used by the recommended techniques, latex particles in the reagent will agglutinate (clump) in the presence of anti-streptolysin O antibodies. No agglutination generally indicates the absence of anti-streptolysin O antibodies (see **Limitations**).

KIT DESCRIPTION

Lorne ASO Latex Kit is a serologic test for the detection of ASO antibodies. All the reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMEN COLLECTION

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8°C for 7 days or for up to 3 months at or below –20°C. Specimens must be free from bacterial contamination, fibrin, gross lipemia and gross haemolysis.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. Materials used to produce the kit were tested at source and found to be negative for HIV 1+2 and HBsAg using approved microbiological tests. However no known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. ASO Positive and Negative Controls must be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. All the reagents must be allowed to reach 18-25°C before use.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the kit is in use.
6. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENTS SUPPLIED

1) ASO Latex Reagent 5.0 mL: Latex particles coated with streptolysin O, pH, 8.2 containing a preservative.
2) ASO Positive Control (1.0 mL, Red cap): Human serum with an ASO concentration > 200 IU/mL containing a preservative.
3) ASO Negative Control (1.0 mL, Blue cap): Animal serum containing a preservative.
4) Pipette-Stirrers.
5) Disposable agglutination Slides.

REAGENTS AND MATERIALS REQUIRED

a) Small glass / plastic test tubes.
b) Serological pipettes.
c) Graduated container.
d) 9 g/L saline solution.

RECOMMENDED QUALITATIVE TECHNIQUE

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the ASO-latex reagent gently before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Swirl the slide gently and after 2 minutes read the results macroscopically. False positive results could appear if the test is read after more than two minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Positive:** Agglutination of latex particles constitutes a positive result and within the accepted limitations of the test procedure, indicates a level of ASO in the specimen > 200 I.U/ml.
2. **Negative:** No visible agglutination of latex particles constitutes a negative result and within the accepted limitations of the test procedure, indicates a level of ASO in specimen < 200 I.U/ml.

RECOMMEDED SEMI-QUANTITATIVE TECHNIQUE

1. The semi-quantitative test can be performed in the same way as the quantitative technique using dilutions of the serum in 9 g/L saline solution.
2. Make doubling dilutions of specimen as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Agglutination of the sera indicates:

Dilution	ASO Levels (I.U. / ml)
1/2	400 (200 x 2)
1/4	800 (200 x 4)
1/8	1600 (200 x 8)

5. Normal levels of ASO in adults is < 200 I.U/ml.

RESULTS

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination, e.g. if this occurs in the 1/8 dilution, the titre is 1600.

INTERPRETATION OF SEMI-QUANITATIVE RESULTS

Positive results may indicate an acute streptococcal infection. In which case the test should be repeated at weekly intervals to determine the progression of infection.

STABILITY OF THE REACTIONS

Slide tests should be interpreted immediately after the 2-minute period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. False positive results may be obtained in conditions such as scarlet fever, acute rheumatoid arthritis, tonsillitis and other streptococcal infections as well as in healthy carriers.
2. Hemoglobin (≤ 10 g/L), bilirubin (≤ 20 mg/dL), lipemia (≤ 10 g/L), rheumatoid factors (≤ 300 IU/mL) do not interfere. Other substances may interfere[7].
3. Early infections in children from 6 months to 2 years may cause false negative results.
4. A single ASO determination does not produce much information about the actual state of the disease. Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
5. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
6. False positive or false negative results may also occur due to:
   a) Contamination of test materials
   b) Improper storage of test materials or omission of reagents
   c) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne ASO Latex Kit is tested by **Recommended Techniques** to ensure suitable reactivity.
3. The ASO-latex sensitivity is calibrated against the WHO 1st International Standard for ASO available from NIBSC.
4. Analytical sensitivity: 200 (± 50) IU/mL, under the described assay conditions.
5. Prozone effect: No prozone effect was detected up to 1500 IU/mL.
6. Diagnostic sensitivity: 98 %.
7. Diagnostic specificity: 97 %.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques.**
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. Haffejee . Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
2. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.
3. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279.
4. The association of Clinical Pathologists 1961. Broadsheet 34.
5. Picard B et al. La Presse Medicale 1983; 23: 2-6.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
100 Tests Per Kit: 5.0 ml ASO Latex 1.0 ml Positive Control 1.0 ml Negative Control	031100A

For the availability of other sizes, please contact:

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
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Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta

LORNE LABORATORIES LTD.
GREAT BRITAIN

RAPID LATEX KIT
DIRECTIONS FOR USE

CRP Latex Kit: For Detection Of C-Reactive Protein (CRP) In Serum.

SUMMARY

C-Reactive Protein (CRP) usually appears in serum of individuals in response to inflammatory conditions and tissue necrosis and disappears when causative conditions subside. It is routinely found in cases of bacterial infection, active rheumatic fever and many malignant diseases and is often seen in association with rheumatoid arthritis, viral infections and tuberculosis. CRP has also been detected in patients following blood transfusions and surgical operations as well as in patients with burns, pemphigus vulgaris and other bullaous lesions.

PRINCIPLE

When used by the recommended techniques, latex particles in the reagent will agglutinate (clump) in the presence of CRP. No agglutination generally indicates absence of CRP (see **Limitations**).

KIT DESCRIPTION

Lorne CRP Latex Test Kit is for the detection of CRP. Test reagent consists of latex particles coated with rabbit Anti-CRP (IgG). All the latex reagents are supplied at optimal dilution for use with all recommended techniques without need for further dilution or addition. For lot reference number and expiry date see **Vial Labels.**

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMEN COLLECTION

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8°C for 7 days or for up to 3 months at or below -20°C. Specimens must be free from bacterial contamination, fibrin, gross lipaemia and gross haemolysis.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Label**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. Materials used to produce the kit were tested at source and found to be negative for HIV 1+2 and HBsAg using approved microbiological tests. However, no known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended the CRP Positive and Negative Controls be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. All the reagents must be allowed to reach 18-25°C before use.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of country where kit is in use. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENTS SUPPLIED

1) CRP Latex Reagent (5 mL): Latex particles coated with goat IgG anti-human CRP, pH, 8.2, containing a preservative.
2) CRP Positive Control (Red cap, 1 mL): Human serum with a CRP concentration > 20 mg/L containing a preservative.
3) CRP Negative Control (Blue cap, 1 mL): Animal serum containing a preservative.
4) Pipette stirrers.
5) Disposable agglutination slide.

MATERIALS AND EQUIPMENT REQUIRED

a) Serological Pipettes.
b) Mechanical rotator capable with adjustable speed of 80-100 rpm.
c) Vortex mixer.
d) Small Glass or Plastic Test Tubes.
e) Distilled or Deionised Water.
f) 9 g/L saline solution.

RECOMMENDED QUALITATIVE TECHNIQUE

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample (Note 1) and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the CRP-latex reagent gently before using and add one drop (50 µL) next to the samples to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a rotary shaker at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read after more than two minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Positive:** Visible agglutination of latex particles constitutes a positive result and within the accepted limitations of the test procedure, indicates a level of CRP in the specimen > 6 mg/l.
2. **Negative:** No visible agglutination of latex particles constitutes a negative result and within the accepted limitations of the test procedure, indicates a level of CRP in the specimen < 6 mg/l.

RECOMMENDED SEMI-QUANTITATIVE TECHNIQUE

1. The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the serum.
2. Make doubling dilutions of the specimen using 9 g/L saline solution as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl
1/16	100 µl 1/8 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Agglutination of the sera indicates:

Dilution	CRP Levels (mg / l)
1/2	12 (6 x 2)
1/4	24 (6 x 4)
1/8	48 (6 x 8)
1/16	96 (6 x 16)

5. Normal levels of CRP in adults are < 6 mg/l.

NOTES

1. High CRP concentration samples may give false negative results (pro-zone effect). Re-test the sample again using a drop of 20 µl.

RESULTS

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination: e.g. if this occurs in dilution 1/8, the titre is 48.

INTERPRETATION OF SEMI-QUANTITATIVE RESULTS

The elevation of CRP levels above normal indicates tissue damage, inflammation, or both with greater reliability. Regular monitoring of CRP levels is often used as a means of assessing disease activity and of guiding therapy. CRP determination is considered of greater practical significance than other indicators of inflammatory disease. Erythrocyte sedimentation rate (ESR) may become elevated as a result of non-inflammatory conditions. In these circumstances inflammatory disease may be excluded if CRP is absent.

STABILITY OF THE REACTIONS

Slide tests should be interpreted immediately after the 2-minute rotation period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. Reactions read beyond the two-minute interval may be invalid.
2. The results obtained from this assay must be considered a part of the differential diagnosis and medical history of the patient.
3. There is no relationship between the strength of reactivity and C-reactive protein levels.
4. Hemoglobin (≤ 10 g/L), bilirubin (≤ 20 mg/dL) and lipemia (≤ 10 g/L), do not interfere. Rheumatoid factors (≥ 100 IU/mL), interfere. Other substances may interfere[7].
5. False positive or false negative results may also occur due to:
   a) Contamination of test materials
   b) Improper storage of test materials or omission of reagents
   c) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne CRP Latex Test Kit is tested by **Recommended Techniques** to ensure suitable reactivity.
3. The CRP-latex sensitivity is calibrated to the Reference Material ERM-DA 472/IFCC.
4. **Analytical sensitivity:** 6 (5-10) mg/L, under the described assay conditions.
5. **Prozone effect:** No prozone effect was detected up to 1600 mg/L (Note 1).
6. **Diagnostic sensitivity:** 95.6 %.
7. **Diagnostic specificity:** 96.2 %.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. Lars-Olof Hanson et al. Current Opinion in Infectious diseases 1997; 10: 196-201.
2. M.M. Pepys. The Lancet 1981; March 21: 653 – 656.
3. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144.
4. Yoshitsugy Hokama et al. Journal of Clinical Laboratory Status 1987; 1: 15 – 27.
5. Yamamoto S et al. Veterinary Immunology and Immunopathology 1993; 36: 257 – 264.
6. Charles Wadsworth et al. Clinica Chimica Acta; 1984: 138: 309 – 318.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

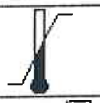
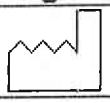
AVAILABLE KIT SIZES

Kit Size	Catalogue Number
100 Tests Per Kit	850100A

For the availability of other sizes, please contact:

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT
England
Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com

TABLE OF SYMBOLS

LOT	Batch Number	IVD	*In-vitro* Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		

LORNE LABORATORIES LTD.
GREAT BRITAIN

CE

RAPID LATEX KIT
DIRECTIONS FOR USE

RF Latex kit: For Detection Of Rheumatoid Factor (RF).

SUMMARY

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the IgG molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosis (sLE) and Sjögren's syndrome, as well as in non-rheumatoid conditions, it's central role lies in aiding in the diagnosis of rheumatoid arthritis

PRINCIPLE

When used by recommended techniques, latex particles in reagent will agglutinate (clump) in presence of rheumatoid factor (RF). No agglutination generally indicates absence of RF (see **Limitations**).

KIT DESCRIPTION

Lorne RF Latex Kit is for the detection of rheumatoid factor. The latex reagent is a suspension of polystyrene latex particles coated with human gamma globulins, which agglutinate in the presence of Rheumatoid Factor (RF). All latex reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMEN COLLECTION

Specimens should be drawn without anticoagulant using an aseptic phlebotomy technique. If testing is delayed, fresh serum can be stored at 2-8°C for 7 days or for up to 3 months at or below –20°C. Specimens must be free from bacterial contamination, fibrin, gross lipeamia and gross haemolysis.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. All the reagents must be allowed to reach 18-25°C before use.
5. Materials used to produce the kit were tested at source and found to be negative for HIV 1+2 and HBsAg using approved microbiological tests. However, no known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended the RF Positive and Negative Controls be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. All the reagents must be allowed to reach 18-25°C before use.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of country where kit is in use. The user must determine the suitability of the kit for use in other techniques.
6. Results obtained with a latex method do not compare with those obtained with the Rose Waaler test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

KIT COMPONENTS SUPPLIED

1) RF Latex Reagent (5 mL): Latex particles coated with human γ-globulin, pH, 8.2, and a preservative.
2) RF Positive Control (Red cap, 1 mL): Human serum with a RF concentration > 30 IU/mL and a preservative.
3) RF Negative Control (Blue cap, 1 mL): Animal serum and a preservative.
4) Pipette-Stirrers.
5) Reusable Agglutination Slide (18 each).

MATERIALS AND EQUIPMENT REQUIRED

a) Glass Test Tubes (10 x 75 mm or 12 x 75 mm).
b) Pasteur and Graduated Pipettes.
c) Vortex mixer.
d) Mechanical rotator with adjustable speed of 80-100 rpm.

RECOMMENDED QUALITATIVE TECHNIQUE

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Shake the RF-latex reagent vigorously or use a vortex mixer before use and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a rotary shaker at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read after more than two minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Positive:** Visible agglutination of latex particles constitutes a positive result and within the accepted limitations of the test procedure, indicates a level of RF in the specimen > 8 IU/ml.
2. **Negative:** No visible agglutination of latex particles in a milky liquid constitutes negative result and within accepted limitations of test procedure, indicates level of < 8 IU/ml RF in specimen.

RECOMMENDED SEMI-QUANTITATIVE TECHNIQUE

1. The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the serum.
2. Make doubling dilutions of serum specimen in 9 g/L saline as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl
1/16	100 µl 1/8 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Agglutination of the sera indicates:

Dilution	RF Levels (I.U/mL)
1/2	16 (8 x 2)
1/4	32 (8 x 4)
1/8	64 (8 x 8)
1/16	128 (8 x 16)

5. Normal levels of RF in adults is < 8 IU/mL

RESULTS

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination: e.g. if this occurs in dilution 1/8, the titre is (8 x 8 IU/mL) = 64 IU/mL.

STABILITY OF THE REACTIONS

Slide tests should be interpreted straight after the 2-minute rotation period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. Using a latex test system, positive results are not always found with every case of clinically defined rheumatoid arthritis, the number of positives reported using various types of latex reagent range from 70% to over 90%.
2. The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
3. Diagnosis should not be solely based on the results of latex method but also should be complemented with a Rose Waaler test along with the clinical examination.
4. Haemoglobin (≤ 10 g/L), bilirubin (≤ 20 mg/dL) and lipaemia (≤ 10 g/L) do not interfere. Other substances may interfere[6].
5. False positive or false negative results may also occur due to:
   a) Contamination of test materials
   b) Improper storage of test materials or omission of reagents
   c) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. The RF latex sensitivity is calibrated against the RF International Calibrator from the WHO (WHO 64/2 Rheumatoid Arthritis Serum).
3. Analytical sensitivity: 8 (6-16) IU/mL, under the described assay conditions.
4. Prozone effect: No prozone effect was detected up to 1500 IU/mL.
5. Diagnostic sensitivity: 100 %.
6. Diagnostic specificity: 100 %.
   The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

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5. Charles M. Plotz 1956; American Journal of Medicine; 21:893 – 896.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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E-mail: info@lornelabs.com

TABLE OF SYMBOLS

LOT	Batch Number	IVD	*In-vitro* Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		

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www.iqnet-certification.com

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ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4265/4**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GRUPPO VACUTEST KIMA

Sede / *Head Office*
Via dell'Industria,12 – 35020 Arzergrande (PD) - Italia
Unità Operative / *Operative Units*
MEUS S.r.l. - Via Leonardo da Vinci, 24B – 26 – 28 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
MEUS S.r.l. - Via dell'Industria, 2 - 16 – 35020 Arzergrande (PD) - Italia
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KIMA S.R.L. - Via Leonardo da Vinci, 22 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
VACUTEST KIMA S.r.l. - Via dell'Industria,12 – 35020 Arzergrande (PD) – Italia
VACUTEST KIMA S.r.l. via L. Da vInci, 22 Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

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ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4**

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GRUPPO VACUTEST KIMA

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Unità Operative / *Operative Units*
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UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

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Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
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044SCM_03_IT

ITALCERT

CERTIFICATO N° 505SGQ03

CERTIFICATE N° 505SGQ03

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.
Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dal Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2017-10-30	2020-10-29

Settore IAF 14 - 29

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SGA N° 020D ISP N° 075E
PRS N° 097C
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P.IVA: 00862050960 - Cod.Fisc.: 07520900155 - R.E.A. MB 1167248

CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI EN ISO 13485:2012

DICHIARAZIONE DI CONFORMITA' CE

CE DECLARATION OF CONFORMITY

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

DICHIARA
DECLARES

Che il dispositivo medico diagnostico in vitro di seguito descritto:
That in vitro diagnostic medical devices described as follows:

SISTEMA SEDI-RATE
SEDI-RATE SYSTEM

PRODOTTI NON STERILI – *NOT STERILE PRODUCTS*

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

- **Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.**
  Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27Th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.
- **I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.**
  The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.
- **Classificazione EDMA (Versione 2007): 2609 Other Other Clinical Instruments**
  EDMA code (Version 2007): 2609 Other Other Clinical Instruments
- **La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.**
  The present Declaration was drafted in accordance with annex III to Directive 98/79/EC.

Rilasciato / *Released*
Canelli, 01.02.2013

Dulio BUONO
Responsabile Assicurazione Qualità

NUOVA APTACA s.r.l.
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P.IVA: 00862050960 - Cod.Fisc.: 07520900155 - R.E.A. MB 1167248

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE
Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
10110	SEDI-RATE Sistema per la determinazione della velocità di eritrosedimentazione composto da provetta Sodio Citrato 0,2ml + Pipetta graduata in PS cristallo	*SEDI-RATE Erytrocyte sedimentation rate system. Test tubes with 0.2ml of Na Citrate + ESR graduated pipettes manufactured in PS crystal.*
10110/P	Pipetta graduata per V.E.S. in polistirolo cristallo	*E.S.R. graduated pipettes in PS crystal*
10110/PR	Provetta con 0,2 ml. di Sodio Citrato per 0,8 ml. di sangue, con tappo rosa, etichettata	Test tube filled with Sodium Citrate 0,2 ml. for 0,8 ml. of blood, with label and pink cap.

Dulio BUONO
Responsabile Assicurazione Qualità

KABE LABORTECHNIK

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers*/Händlers**: Name and address of the manufacturer*/distributor**:	**KABE LABORTECHNIK GmbH** **Jägerhofstraße 17** 51588 Nümbrecht-Elsenroth **Deutschland / Germany**

Wir erklären in alleiniger Verantwortung* bzw. aufgrund der uns vom Hersteller vorliegenden Informationen**,
dass die In-Vitro-Diagnostika der Produktgruppe /
We declare under our sole responsibility* respectively according to the information of the manufacturer**
that the in-vitro-diagnostica of product group

kapillare Blutentnahmesysteme	**capillary blood collection systems**
• **Kapillarblutentnahmesystem (GK)***	• **capillary blood collection system (GK)***
• **kapillare Probenbehältnisse aus Kunststoff***	• **capillary sample containers made of plastic***
• Blutgaskapillaren (BK)	• blood gas capillaries (BK)
• Hämatokritkapillaren (HK)	• haematocrit capillaries (HK)
• end-to-end Kapillaren (EK)	• end-to-end capillaries (EK)
• **kapillare Probenbehältnisse aus Glas****	• **capillary sample containers made of glass****
• Blutgaskapillaren (BK)	• blood gas capillaries (BK)
• Hämatokritkapillaren (HK)	• haematocrit capillaries (HK)
• end-to-end Kapillaren (EK)	• end-to-end capillaries (EK)
• Mikro-Kapillar-Pipetten mit Ringmarke (RM)	• micro-capillary pipettes with ring mark (RM)

der Klasse / of class	**Andere IVD-Produkte** **Other IVD-devices**

den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE LABORTECHNIK GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. This declaration is valid for the batches released by KABE LABORTECHNIK GmbH.

Konformitätsbewertungsverfahren: Conformity assessment procedure:	**Richtlinie 98/79/EG Anhang III** **Directive 98/79/EC Annex III**

Nümbrecht-Elsenroth, 26.07.2018

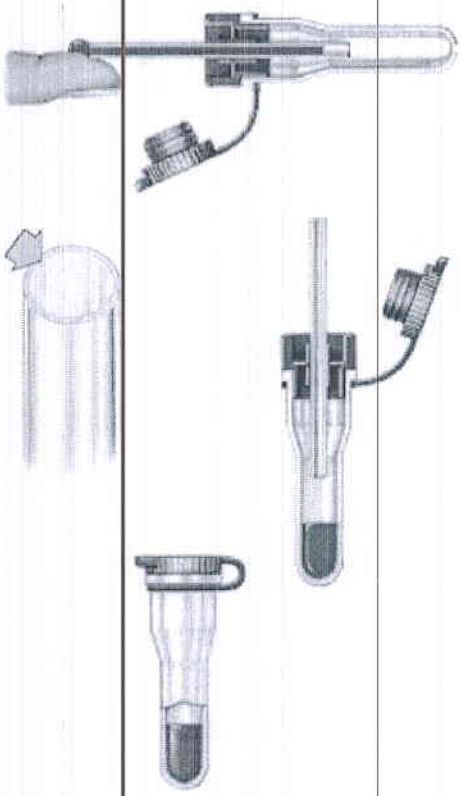
KABE LABORTECHNIK GmbH
Jägerhofstraße 17
D-51588 Nümbrecht-Elsenroth
☎ +49 (0) 2293 / 596

André Kolpe, Geschäftsführer / Managing director

Capillary blood collection system
Capillary blood collection GK

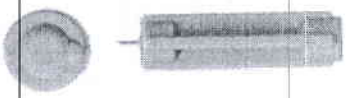
Capillary blood collection GK
It consists of a prepared test vessel and a prepared plastic end-to-end collection capillary with stopper.
• Easy handling
• Plastic capillary* with exact filling volume; complete inner surface prepared, unbreakable
• Collection vessel serves as centrifugal vessel; prepared for all common tests
• Light protected, tinted vessels for bilirubin analyses
* with conformity certificate in accordance with the Weights and Measurement Regulations
Fill the capillary with capillary blood from a horizontal position.
After filling let the blood flow into the vessel from a vertical position (shake out remaining blood).
Remove the capillary, press on the attached stopper and mix or centrifuge.

077003	**EDTA 100 µl** Packing unit: 100 pcs in bag, 4,000 pcs in box Ø 11/8 x 39 mm



LANCETS 28G for 23915, 23919 - sterile

Code:	**23916**
Category:	**Lancets**
Unit of sale:	**box of 100 pcs.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**II A**
NSIS:	**1369290**
CND:	**V0104**
EAN13:	**8023279239164**



Description:

Lancets are fine needles that can be used with device codes 23915, 23919 and most of lancet devices in the market to draw a blood sample for glucose testing.

Multilanguage box: GB, FR, IT, DE, ES, PT, GR, PL, Arabic.

Gima S.p.A. Via Marconi, 1 - 20060 Gessate (MI) Tel. +39 02 953854209 - Fax.+39 02 35380056

北京瑞成医疗器械有限公司
Beijing Ruicheng Medical Supplies Co., Ltd.

EC Declaration of Conformity

Manufacturer:
Name: Beijing Ruicheng Medical Supplies Co., Ltd.
Address: No. 558 Zhangzikou, Yangsong Town, Huairou District, 101400 Beijing, China

Whose single Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, herewith declare that the product

Disposable Lancets

Models: 21G Ⅰ, 23G Ⅰ, 25G Ⅰ, 26G Ⅰ, 27G Ⅰ, 28G Ⅰ, 30G Ⅰ, 33G Ⅰ;
21G Ⅱ, 23G Ⅱ, 25G Ⅱ, 26G Ⅱ, 27G Ⅱ, 28G Ⅱ, 30G Ⅱ, 33G Ⅱ;
21GⅣ, 23GⅣ, 25GⅣ, 26GⅣ, 27GⅣ, 28GⅣ, 30GⅣ, 33GⅣ;
21G Ⅴ, 23G Ⅴ, 25G Ⅴ, 26G Ⅴ, 27G Ⅴ, 28G Ⅴ, 30G Ⅴ, 33G Ⅴ;
21GM3, 23GM3, 25GM3, 26GM3, 27GM3, 28GM3, 30GM3, 33GM3;
21GM4, 23GM4, 25GM4, 26GM4, 27GM4, 28GM4, 30GM4, 33GM4;

UMDNS-Code:10440

Meet the provisions of Directive 93/42/EEC which apply to them.
The medical device has been assigned to Class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.
Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DD 60141252 0001
Issue date: 2019-08-05
Expiry date: 2024-05-27

Following the procedure relating to the EC Declaration of Conformity set out in annex II of directive 93/42/EEC.
This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: Beijing Ruicheng Medical Supplies Co., Ltd.
Address: No. 558 Zhangzikou, Yangsong Town, Huairou District, 101400 Beijing, China

Beijing. Aug. 5, 2019.
Beijing
Place, date

Yuechao Li
Name: Yuechao Li General Manager
Legally binding signature, function

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, г. Москва, ул. Госпитальный вал, д.5, стр.7А, пом.VIII
Для писем: 105094, г. Москва, а/я 26
тел/факс: (495) 988-76-67, 360-61-46, 360-72-19
http:\\www.vinar.ru e-mail: main@vinar.ru

Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

ПАСПОРТ КАЧЕСТВА

Индикаторы химические одноразовые воздушной стерилизации МедИС-В-Винар по ТУ 9398-032-11764404-2004

Регистрационное удостоверение
№ ФСР 2009/05017
от 27.08.2019 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н18087
от 18.09.2019 г.

Модификация : ***«МедИС-В-180/60»***

Партия ***9177109*** ***Дата изготовления*** ***Октябрь 2019 г.***

Гарантийный срок ***3 года***
Условия эксплуатации и хранения в соответствии с инструкцией производителя
Код ОКПД 2 32.50.50.190

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-032-11764404-2004	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный за контроль качества Чуванова А. А.

М.П. ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА