

Anexa nr. 7
la Documentația standard nr. _____
din “_____” _____ 20____

CERERE DE PARTICIPARE

Către **CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SĂNĂTATE**

Stimați domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, nr. [ocds-b3wdp1-MD-1759225892563](#) din 30.09.2025, privind ***Achiziționarea Reagenți pentru PCR și Controalelor Externe de Calitate conform necesităților IMSP Centrul Republican de Diagnosticare Medicală pentru anul 2026***, noi Medist Grup SRL, am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavând obiecții la documentația de atribuire.

Data completării 13.11.2025

Cu stimă,
Ofertant/candidat
MEDIST GRUP SRL
Gabriela-Cristina Anghel

ORDIN DE PLATA		Nr.	116	DATA EMITERII	12 noiembrie 2025	TIP DOC : 1	
PLATITI:	851-10	LEI	opt sute cinci zeci si unu lei .10 bani				
PLATITOR	(R) SOCIETATEA CU RASPUNDERE LIMITATA MEDIST GRUP			CODUL IBAN:	MD59EX0000002251874012MD		
				COD FISCAL:	1018600004516		
PRESTATORUL PLATITOR:		B.C. "EXIMBANK" S.A. SUCURSALA NR.20 CHISINAU					
BENEFICIAR	(R) Mf-TR Chisinau bugetul de stat			CODUL IBAN:	MD23TRPCCC518430B01859AA		
				COD FISCAL:	1016601000212		
PRESTATORUL BENEFICIAR:		MINISTERUL FINANTELOR - TREZORERIA DE STAT					
DESTINATIA PLATII				TIPUL TRANSFERULUI NORMAL/URGENT			
/P102/851.10 Plata pentru garantia pentru oferta in cuantum de 2 procente pt LP nr.21482218 din 30.09.2025				<div>N</div> <div>L.S.</div>			
COD TRANZACTIE:		DATA PRIMIRII:		DATA EXECUTARII:			
101		12 noiembrie 2025		12 noiembrie 2025 15:33:35			
SEMNATURA BANCII:		FE94E32E0193CA0773AAFF2672ECE891					
				SEMNATURA BANCII		SEMNATURILE EMITENTULUI	
						GABRIELA-CRISTINA ANGHEL SOHg3JIQYjZ7GJleY4XCF/Plxqh+MuBXXK1f3AkY= GABRIELA-CRISTINA ANGHEL SOHg3JIQYjZ7GJleY4XCF/Plxqh+MuBXXK1f3AkY=	
				Inițiat în sistemul Eximbank Online și autorizat cu Semnătura Digitală			
MOTIVUL REFUZULUI:							

I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare a unităților de drept (DÎUD)

**Extras
din Registrul de stat al persoanelor juridice
nr. 187942 din 23.09.2025**



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

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

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

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

Data înregistrării de stat: **02.02.2018**

Sediu: **MD-2012, strada Mitropolit Gavriil Bănulescu-Bodoni 25, ap.(of.) 33, mun. Chișinău, Republica Moldova**

Genurile de activitate:

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

Capitalul social: **373026 Lei**

Administrator(i): **ANGHEL GABRIELA-CRISTINA**

Asociați:

- 1. "MEDIST IMAGING & P.O.C." S.R.L., partea socială 6244 Euro, ce constituie 33.0004%**
- 2. "MEDIST LIFE SCIENCE" S.R.L., partea socială 6244 Euro, ce constituie 33.0004%**
- 3. "MEDIST" S.R.L., partea socială 6433 Euro, ce constituie 33.9993%**

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

Prezentul extras este eliberat în temeiul art. 34 al Legii nr.220/2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de 23.09.2025

Specialist coordonator

Alina Dobrovolschi

tel. 022-20-7892



AGENȚIA SERVICII PUBLICE A REPUBLICII MOLDOVA

Departamentul înregistrare și licențiere a unităților de drept

DECIZIE

privind înregistrarea persoanei juridice

02.02.2018

Dosar Nr. 1018600004516

**Serviciul înregistrare a unităților de
drept mun. Chișinău**

Prin cererea depusă la 31.01.2018 s-a solicitat înregistrarea
Societatea cu Răspundere Limitată "MEDIST GRUP"

Examinînd actele prezentate:

1. Proces-verbal al adunării de constituire din 31.01.2018
2. Actele de constituire MEDIST LIFE SCIENCE
3. Hotărârea Adunării Generale MEDIST LIFE SCIENCE nr. 1 din 15.01.2018
4. Actele de constituire MEDIST S.A.
5. Hotărârea Adunării Generale a acționarilor Medist S.A. nr. 1 din 15.01.2018
6. PROCURĂ nr. 149 din 26.01.2018, CHIRICĂ OLESEA
7. Actele de constituire MEDIST IMAGING S.R.L.
8. Hotărârea Adunării Generale MEDIST IMAGING S.R.L. nr. 1 din 15.01.2018
9. Declarație nr. 32 din 22.01.2018
10. Certificat de verificare și rezervare a denumirii nr. 375156 din 21.12.2017
11. Scrisoare de garanție din 16.01.2018
12. Statut
13. Ordine de încasare din 31.01.2018
14. PROCURĂ nr. 117 din 22.01.2018, CHIRICĂ OLESEA
15. PROCURĂ nr. 148 din 26.01.2018, CHIRICĂ OLESEA

și constatînd, că sînt respectate cerințele legale ce țin de constituirea și înregistrarea persoanei juridice, în temeiul art. 11 al Legii nr. 220-XVI din 19.10.2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali, registratorul

DECIDE:

1. A admite cererea de înregistrare.
2. A înregistra persoana juridică și a consemna în Registrul de stat al persoanelor juridice următoarele date:

Numărul de identificare de stat: **1018600004516** din 02.02.2018

Forma juridică de organizare: Societate cu răspundere limitată

Denumirea: Societatea cu Răspundere Limitată "MEDIST GRUP"

Sediul: MD-2012, str. Mitropolit Gavriil Bănulescu-Bodoni, 25, of. 33, mun. Chișinău,
Republica Moldova

Administrator: ANGHEL GABRIELA-CRISTINA, anul nașterii 19.12.1967, cet. ROMÂNIA,
PAȘAPORT NAȚIONAL AL CETĂȚEANULUI STRĂIN ROU 054481583 eliberat la
data de 27.02.2017, domiciliu: str. bd. Timișoara, 41/P14, ap. 31, București, România

Genurile principale de activitate:

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

Capitalul social: 20790,6 lei.

Fondator(i):

1. "MEDIST LIFE SCIENCE" S.R.L., înregistrat(ă) la 17.07.2008, numărul de înregistrare 24205119, sediul: str. Ion Urdăreanu, 34, et. 3, București, România, parte socială în valoare de 330 EUR (33%)
2. "MEDIST IMAGING & P.O.C." S.R.L., înregistrat(ă) la 17.07.2008, numărul de înregistrare 24205100, sediul: str. Ion Urdăreanu, 34, et. 1, București, România, parte socială în valoare de 330 EUR (33%)
3. "MEDIST" S.A., înregistrat(ă) la 05.01.1995, numărul de înregistrare 6705884, sediul: str. Ion Urdăreanu, 34A, București, România, parte socială în valoare de 340 EUR (34%)

Termenul de activitate al întreprinderii este nelimitat.

3. Prezenta Decizie este întocmită în două exemplare, care au aceeași valoare juridică, dintre care un exemplar se păstrează la Agenția Servicii Publice în dosarul de evidență al persoanei juridice, iar celălalt se eliberează solicitantului.

Registrator



Dragomir Ala



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№

1537516

Din
От

12.11.2025 15:37



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1018600004516

Denumirea

Наименование

Societatea cu Răspundere Limitată "MEDIST GRUP"



ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL



VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

27.11.2025 15:37



Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответствие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la 12.11.2025 15:37

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022

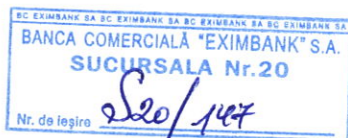


Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are același valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Государственной Службой Электронной Подписью (msign.gov.md)



EXIMBANK



21. MAR. 2025

CERTIFICAT

Prin prezentul, B.C. "EXIMBANK" S.A., Sucursala nr.20, confirmă faptul deținerii de către compania **„MEDIST GRUP” SRL, IDNO 1018600004516**, a următorului cont de decontare în valuta MDL, activ la data de 21.03.2025:

Valuta	Nr. Cont	Cod IBAN
MDL	2251874012MD	MD59EX0000002251874012MD

Certificatul este eliberat pentru a fi prezentat la cerere.

Coordonator, Sucursala nr. 20
Postu Diana



Ex.: Belecci Lilia
Tel.: 022 301-244

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2024 - 31.12.2024

Entitatea: MEDIST GRUP S.R.L.

Cod CUIÎO: 41247072

Cod IDNO: 1018600004516

Sediul:

MD:

Raionul(municipiul): 105, DDF BUIUCANI

Cod CUATM: 0120, SEC.BUIUCANI

Strada: Mitropolit Gavriil Banulescu-Bodoni nr.25 of.33

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice

Forma de proprietate: 23, Proprietatea statelor străine

Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:

Telefon: 022849495

WEB: www.medist.md

E-mail: natalia.mutu@medist.md

Numele și coordonatele al contabilului-șef: DI (dna) Mutu Natalia Tel. 068681147

Numărul mediu al salariaților în perioada de gestiune: 5 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Gabriela Anghel

Unitatea de măsură: leu

BILANȚUL

la 31.12.2024

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
A.	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:	021		
	2.1. concesiuni, licențe și mărci			
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		

2.4. alte imobilizări necorporale	024		
3. Fond comercial	030		
4. Avansuri acordate pentru imobilizări necorporale	040		
Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
II. Imobilizări corporale			
1. Imobilizări corporale în curs de execuție	060		
2. Terenuri	070		
3. Mijloace fixe, total	080	3859991	4145923
din care:	081		
3.1. clădiri			
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	3854288	4143722
3.4. mijloace de transport	084		
3.5. inventar și mobilier	085		
3.6. alte mijloace fixe	086	5703	2201
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120	141992	0
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	4001983	4145923
III. Investiții financiare pe termen lung			
1. Investiții financiare pe termen lung în părți neafiliate	140		
2. Investiții financiare pe termen lung în părți afiliate, total	150		
din care:	151		
2.1. acțiuni și cote de participație deținute în părțile afiliate			
2.2 împrumuturi acordate părților afiliate	152		
2.3 împrumuturi acordate aferente intereselor de participare	153		
2.4 alte investiții financiare	154		
Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
IV. Creanțe pe termen lung și alte active imobilizate			
1. Creanțe comerciale pe termen lung	170		
2. Creanțe ale părților afiliate pe termen lung	180		
inclusiv: creanțe aferente intereselor de participare	181		
3. Alte creanțe pe termen lung	190		

	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	4001983	4145923
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	63405	32788
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	765931	1226919
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	829336	1259707
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	2559140	2204438
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	991266	891719
	4. Creanțele ale personalului	330	300	0
	5. Alte creanțe curente	340	1838152	1684147
	6. Cheltuieli anticipate curente	350	10942	17093
	7. Alte active circulante	360	27708	12417
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	5427508	4809814
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		
	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	3229017	5589247
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	9485861	11658768

	TOTAL ACTIVE (rd.230 + rd.420)	430	13487844	15804691
	P A S I V			
	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	1. Capital social	440	373026	373026
	2. Capital nevărsat	450	()	()
	3. Capital neînregistrat	460		
	4. Capital retras	470	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	373026	373026
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	5720650	5720650
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	1566783
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	5720650	7287433
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	6093676	7660459
C.				
	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640	1307469	376589
	din care:			
	2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643	1307469	376589
	3. Datorii comerciale pe termen lung	650	299803	258645
D.				

	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700	1607272	635234
E.	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720	951672	1129768
	din care:			
	2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723	951672	1129768
	3. Datorii comerciale curente	730	100772	17323
	4. Datorii față de părțile afiliate curente	740	4692920	6298191
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	0	56617
	6. Datorii față de personal	760	0	127
	7. Datorii privind asigurările sociale și medicale	770	28990	0
	8. Datorii față de buget	780	12542	6972
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810		
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	5786896	7508998
F.	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	13487844	15804691

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2024 până la 31.12.2024

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune
------------	---------	----------------------

		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	20271056	25169645
din care:			
venituri din vânzarea produselor și mărfurilor	011	19719964	24721251
venituri din prestarea serviciilor și executarea lucrărilor	012	211868	74032
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	339224	374362
Costul vânzărilor, total	020	15060163	17842250
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	15060163	17842250
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	5210893	7327395
Alte venituri din activitatea operațională	040	66300	151353
Cheltuieli de distribuire	050	146520	223513
Cheltuieli administrative	060	4367490	4538666
Alte cheltuieli din activitatea operațională	070	570712	788039
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	192471	1928530
Venituri financiare, total	090	991278	1438847
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093		
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	991278	1438847

Cheltuieli financiare, total	100	804089	1471126
din care:	101		
cheltuieli privind dobânzile			
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	804089	1471126
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	187189	-32279
Venituri cu active imobilizate și excepționale	120	281416	0
Cheltuieli cu active imobilizate și excepționale	130	200390	0
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140	81026	0
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	268215	-32279
Profit (pierdere) până la impozitare (rd.080 + rd.150)	160	460686	1896251
Cheltuieli privind impozitul pe venit	170	142346	329468
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	318340	1566783

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2024 până la 31.12.2024

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	Capital social și neînregistrat					
	1. Capital social	010	373026			373026
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	373026			373026
II.	Prime de capital	070				
III.	Rezerve					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				

	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
IV.	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130	5720650			5720650
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	1566783		1566783
	4. Profit utilizat al perioadei de gestiune	150	X	()	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	5720650	1566783		7287433
V.	Rezerve din reevaluare	170				
VI.	Alte elemente de capital propriu	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190	6093676	1566783		7660459

SITUAȚIA FLUXURILOR DE NUMERAR
de la 01.01.2024 până la 31.12.2024

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010	24793777	27711653
Plăți pentru stocuri și servicii procurate	020	19703580	19068111
Plăți către angajați și organe de asigurare socială și medicală	030	1905611	1811062
Dobânzi plătite	040	19210	35240
Plata impozitului pe venit	050	169911	329468
Alte încasări	060		
Alte plăți	070	3499117	3370499
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	-503652	3097273
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobânzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		

Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150	800000	
Plăți aferente rambursării creditelor și împrumuturilor	160	1375308	774160
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200	-575308	-774160
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	-1078960	2323113
Diferențe de curs valutar favorabile (nefavorabile)	220	146394	37117
Sold de numerar la începutul perioadei de gestiune	230	4161583	3229017
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	3229017	5589247

Documente atașate - Notă explicativă (fișierul pdf)

 Nota explicativa la Situatii financiare 2024.signed.pdf

Recipisa

Respondent

Codul fiscal: 1018600004516, denumire: MEDIST GRUP S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2024

Data prezentarii: 30.05.2025

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 30.05.2025 11:15:51

**DECLARAȚIE
privind valabilitatea ofertei**

Către: **CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE**

Stimați domni,

Ne angajăm să menținem oferta valabilă, **Achiziționarea dispozitivelor medicale (analizatoare) conform necesităților instituțiilor medico-sanitare publice (listă suplimentară 3)**, pentru o durată de 160 zile, (una sută șasezeci), respectiv până la data de 15/04/2026 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 13.11.2025

**Cu stimă,
Ofertant/candidat
MEDIST GRUP SRL
Gabriela-Cristina Anghel**

DECLARAȚIE

Subsemnata Gabriela Anghel, reprezentant împuternicit al MEDIST GRUP S.R.L, cu sediul în mun. Chișinău, str. M.G. Bănulescu-Bodoni 25, Oficiul 33, declar pe propria răspundere că:

- termenul de valabilitate restant (la momentul livrării) conform specificației tehnice solicitate pentru fiecare lot în parte, va constitui nu mai puțin de 50% din termenul total de valabilitate indicat, dar nu mai puțin de 1 an.
- eșantioane (mostre) vor fi prezentate în 2 bucăți – în termen de 10 zile de la solicitarea în scris a autorității contractante, într-o cutie pe care se va indica denumirea operatorului economic și numărul procedurii de achiziție publică. Se va prezenta lista mostrelor incluse în cutie și numărul de lot al acestora cu scrisoare de însoțire semnată. Pe fiecare produs în parte va fi indicat numărul lotului și denumirea operatorului economic.
- seturile vor fi livrate în ambalaj original, securizat, marcat și etichetat de producător, fără preambalare. Date de identitate (denumirea, numărul lotului, seria, termenii de valabilitate, condiții de păstrare) ale produsului indicate pe ambalaj vor coincide în mod obligatoriu cu cele de pe etichetele componentelor incluse în set. Instrucțiunile de utilizare a truselor vor conține caracteristicile de performanță și calitate: sensibilitate, liniaritate, specificitate, reproductibilitate și interferență. Instrucțiunile vor fi prezentate în limba de stat sau limba rusă.
- livrarea produselor la destinatar se va efectua cu respectarea condițiilor de păstrare și transportare pe tot parcursul lanțului de transportare de la fabricant la beneficiar.
- se va asigura 12 luni de garanție a produselor fără nicio plată suplimentară din data livrării.
- bunurile ce urmează a fi achiziționate nu necesită înregistrare în Registrul de Stat al Dispozitivelor Medicale.

Data completării 13.11.2025

Cu stimă,

Ofertant/candidat

Gabriela-Cristina Anghel

(semnătura autorizată)

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Radox Laboratories Limited
55 Diamond Road
Crumlin
County Antrim
BT29 4QY
United Kingdom

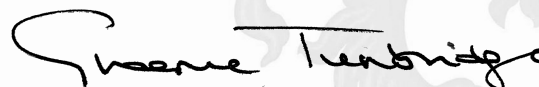
Holds Certificate Number:

MD 686778

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

The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls and in-vitro diagnostic analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-03-19

Latest Revision Date: 2022-11-02

Effective Date: 2022-11-06

Expiry Date: 2025-11-05



Page: 1 of 3

...making excellence a habit.™

Certificate No: **MD 686778**

Location	Registered Activities
Randox Laboratories Limited 55 Diamond Road Crumlin County Antrim BT29 4QY United Kingdom	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls and in-vitro diagnostic analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Randox Laboratories Limited 34 Diamond Road Crumlin County Antrim BT29 4QX United Kingdom	The design, development and manufacture of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Randox Laboratories Limited 36 Largy Road Crumlin County Antrim BT29 2RN United Kingdom	The design, development, manufacture, service and distribution of in-vitro diagnostic analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Randox Laboratories Limited 44 Largy Road Crumlin County Antrim BT29 4RN United Kingdom	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls and in-vitro diagnosis analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.

Original Registration Date: 2018-03-19

Effective Date: 2022-11-06

Latest Revision Date: 2022-11-02

Expiry Date: 2025-11-05

Page: 2 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: **MD 686778**

Location	Registered Activities
Randox Teoranta Meenmore Dungloe Donegal F94 TV06 Ireland	The design, development, manufacture and distribution of in-vitro diagnostic analysers, manufacture of in-vitro diagnostic reagents, used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Randox Science Park 30 Randalstown Rd Antrim BT41 4FL United Kingdom	The design and development of reagents, calibrators and controls and the manufacture of calibrators and controls used in the diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identifications of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Randox Laboratories Ltd 61 Largy Road Crumlin County Antrim BT29 4RR United Kingdom	The design, development and manufacture of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, cardiac markers, protein metabolism, endocrine disorders, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.

Original Registration Date: 2018-03-19

Latest Revision Date: 2022-11-02

Effective Date: 2022-11-06

Expiry Date: 2025-11-05

Page: 3 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate of Accreditation



Quality Control for Molecular Diagnostics (QCMD)

Proficiency Testing Provider No. 4385

**is accredited in accordance with International Standard ISO/IEC 17043:2023
- Conformity assessment - General requirements for proficiency testing**

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

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

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

A handwritten signature in black ink, appearing to read "M Gantley", is written over a horizontal line.

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

Initial Accreditation: 19 May 2011
Certificate Issued: 1 November 2024



Scan QR Code to
verify



EQA/PT SCHEMES FOR MOLECULAR INFECTIOUS DISEASE TESTING

2025 CATALOGUE

EQA FOR MOLECULAR INFECTIOUS DISEASE TESTING

QCMD (Quality Control for Molecular Diagnostics) is an independent External Quality Assessment (EQA) / Proficiency Testing (PT) provider specialising in molecular testing of a wide range of infectious diseases.

1	INTRODUCTION TO QCMD EQA SCHEMES
3	BENEFITS
4	HOW IT WORKS
5	EQA GROUPS (INDEX)
15	VIRAL EQA SCHEMES
42	BACTERIAL EQA SCHEMES
53	FUNGAL EQA SCHEMES
55	PARASITIC EQA SCHEMES
56	MULTI-PATHOGEN/SYNDROMIC EQA SCHEMES
64	EQA PILOT STUDIES
73	APPENDIX

AN INTRODUCTION TO THE QCMD EQA SCHEMES

The aim of QCMD's External Quality Assessment (EQA) schemes is to help monitor and improve laboratory quality by assessing a laboratory's use of molecular testing for infectious diseases. The EQA schemes are both educational and regulatory in application and support continuous quality improvement, as well as assist laboratory accreditation / certification to ISO15189 or equivalent.

Who can participate?

The EQA schemes are provided global either directly from QCMD or through one of many QCMD approved QA collaborators and distributors. To register or find out more go to www.QCMD.org

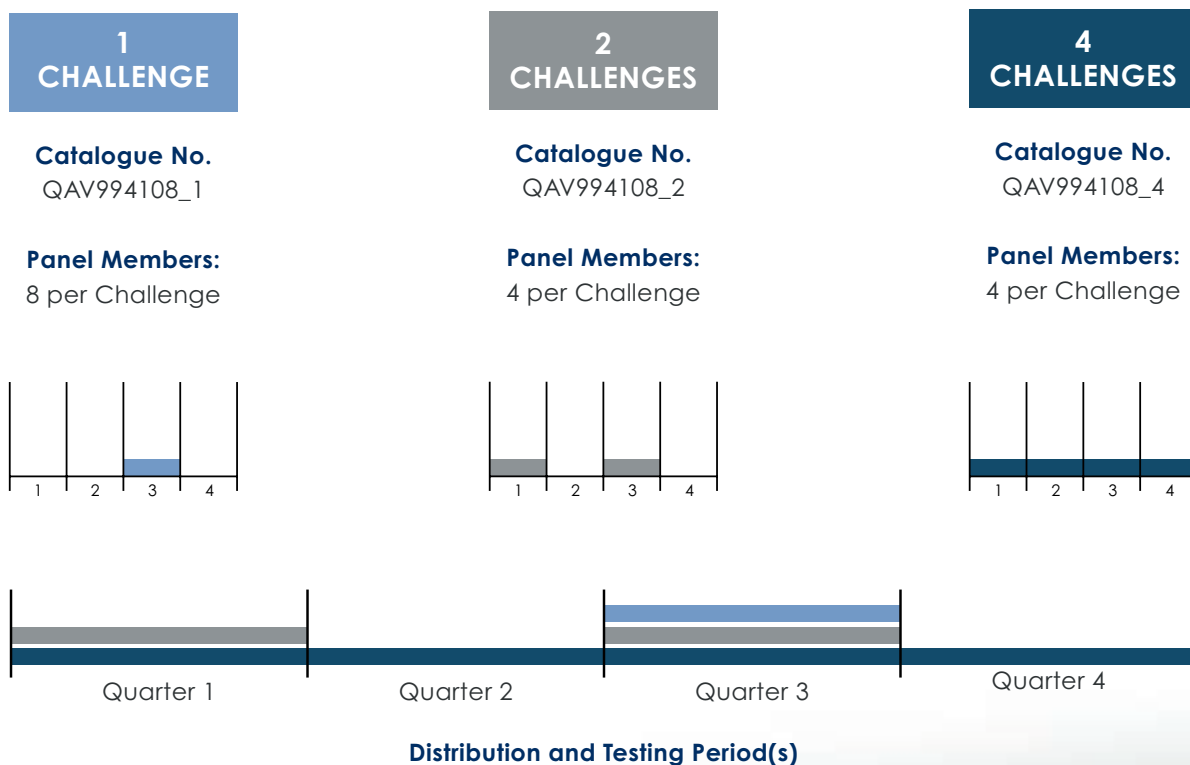
The EQA scheme format

All individual QCMD EQA schemes have their own design specifications which are agreed by the QCMD scientific experts / advisors for each scheme. The distribution frequencies (number of challenges per year) within an EQA scheme often vary in different countries due to regional regulatory requirements. As a result, QCMD offers a range of options from a single challenge per year to a 4 challenge EQA format per year depending on the EQA scheme.

Participants can select which EQA format is best for their laboratory and regulatory requirements.

For more details on the format of each of the EQA schemes see the individual EQA specifications within the catalogue or visit the QCMD website.

For example, the HIVRNA, HBV, and HCV BBV viral load EQA schemes are provided with the option of either 1, 2 or 4 challenges per year.



An Introduction to the QCMD EQA Schemes

EQA Distribution schedule

The EQA schemes are distributed at set dates throughout the year. An outline of the distribution schedule is provided in appendix I and further details regarding the annual distribution schedule are provided on registration through the QCMD website (www.qcmd.org). On receipt of the EQA panel the laboratory has a defined period of time to test the panel and return their results to QCMD through the secure web-based portal. An outline of the testing periods is also provided within appendix I.

QCMD EQA Reports & feedback

After close of the EQA results return phase, Laboratories receive an individual report for the EQA challenge / scheme they have participated in. This provides an overview of their performance in relation to their method / technology type peer group and where appropriate the overall consensus from all participants within the EQA scheme.

On completion of the EQA scheme, a supplementary report may be provided (depending on the EQA scheme).

The supplementary report includes any relevant additional information regarding the recent EQA scheme, and where appropriate any Scientific Expert commentary / feedback on the overall EQA scheme results. Where required, National EQA providers or country specific EQA groups are also provided with an additional country specific EQA report.

Further information

For further details register on line and visit your profile area, download the QCMD participant manual at www.QCMD.org

BENEFITS



EXTENSIVE PROGRAMME OFFERING

Boasting the largest selection of molecular EQA programmes for infectious disease testing, you are sure to find what you're looking for.



FREQUENCY

Choose between one, two and four challenges* per year to suit your laboratory requirements. Reports are available within 2 weeks of the submission deadline (up to 4 weeks for the drug resistance / sequence based schemes), ensuring any corrective actions can be taken quickly.



HIGH QUALITY MATERIAL

The availability of whole pathogen samples in clinically relevant matrices mimics the performance of patient samples and ensures samples can be used to effectively monitor the performance of the entire testing process.



INTERNATIONAL ACCREDITATION

Where appropriate the EQA schemes are accredited to ISO 17043 highlighting the superior quality and organisation of the QCMD scheme.



ONLINE EQA MANAGEMENT SYSTEM

IT EQA Management System (ITEMS) provides an online tool to easily manage all EQA activities from scheme registration to submission of results and provision of EQA reports.



HIGH LEVEL OF PARTICIPATION

With over 15,000 participant registrations in more than 120 countries, peer groups are maximised, increasing statistical validity.



COMPREHENSIVE REPORTS

Individual reports are provided with each EQA challenge. In line with the requirements of ISO 17043, they provide the laboratories with their results and performance assessment in relation to their EQA assessment group (peer review group).

Supplementary reports which include scientific expert commentary may be provided at the end of the EQA cycle if appropriate.

*programme dependent

HOW IT WORKS

The QCMD catalogue is extensive with more than 100 EQA/PT schemes and pilot studies covering over 300 target organisms.

The following diagram provides an overview of the schemes operation.



EQA GROUPS

BLOODBORNE VIRUS

The Bloodborne Virus (BBV) group of QCMD External Quality Assessment (EQA) schemes consists of pathogens that are detected from the blood. This includes human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) B19 virus (B19) and more recently hepatitis A virus (HAV), hepatitis E virus (HEV) and hepatitis D virus (HDV).

To compliment the detection and viral load determination schemes above a range of genotyping and drug resistance BBV EQA schemes are available.

For the drug resistance BBV EQA schemes different current resistance markers are included and emphasis is placed on the determination and interpretation of these resistance markers.

Page Number		Page Number	
B19 virus	15	Hepatitis C virus	25
BBV Dried Blood Spots	65	Hepatitis D virus	26
HBV Drug Resistance	21	Hepatitis E virus	26
HBV Genotyping	22	HIV-1 (DNA)	28
HCV Drug Resistance	23	HIV-1 (RNA)	28
HCV Genotyping	24	HIV-1 Drug Resistance	29
Hepatitis A virus	24	HIV-1 Drug Resistance (Integrase)	29
Hepatitis B virus	25	HIV-2	30

CENTRAL NERVOUS SYSTEM

Infections of the Central Nervous System (CNS) can occur indirectly via the blood following damage to the blood brain barrier or directly through intraneuronal routes. Encephalitis and meningitis are important CNS infections which can have viral, bacterial or parasitic origins.

Viral encephalitis can occur as a result of acute infection or as the consequence of latent infection. Common viral causes include herpes simplex virus (HSV), specific enteroviruses (EV), JC and BK virus, as well as Varicella-Zoster virus (VZV). Bacterial infections within the CNS such as meningitis can be a result of direct infection of the brain or may be due to underlying diseases which can lead to secondary CNS infection. Parasites such as *Toxoplasma gondii* can also cause CNS infections particularly in immunocompromised individuals.

In recent years significant advances have been made in understanding CNS pathogenesis with the development of molecular technologies for the diagnosis and monitoring of disease, the introduction of effective treatment therapies and, in some cases, the development of vaccines (e.g. Japanese encephalitis & rabies). The range of QCMD EQA schemes within this area focus on pathogens known to play a significant clinical role in CNS infection. The general aim of this group of EQA schemes is to assess the laboratories' ability in the detection and determination of the selected pathogen. Where appropriate pathogen load estimation is also evaluated.

	Page Number		Page Number
Arthropod-borne viruses	56	Herpes simplex virus 1 & 2	27
BK virus	16	Herpes simplex virus Drug Resistance	27
Borrelia burgdorferi spp. (Lyme Disease)	43	JC virus	35
Central nervous system CNS I (Viral Meningitis and Encephalitis)	57	Measles / Mumps	35
Central nervous system CNS II (Non-Viral Meningitis and Encephalitis)	57	Parechovirus	37
Chikungunya virus	16	Toxoplasma gondii	55
Dengue virus	19	Varicella-Zoster virus	40
Enterovirus	19	West Nile virus	40
Enterovirus typing	20	Zika virus	41

EQA GROUPS

CONGENITAL INFECTIONS

The term congenital infection is used to describe those infections transmitted from mother to child either during pregnancy (Transplacental infection) or immediately after childbirth. They can be caused by viruses, bacteria and on occasion parasites. The ability of a particular pathogen to cross the placenta and infect the foetus /embryo is dependent on many factors including the mother's immune status. Primary infections during pregnancy can result in spontaneous abortion or major developmental disorders if undetected and left untreated.

In recent years the diagnosis of congenital infections has been significantly improved by the ability to obtain clinical samples such as blood through chorionic villus sampling. In addition, the application of molecular technologies has helped significantly in the diagnosis, monitoring, and treatment rationale. CMV Dried Blood Spots is one of the EQAs provided in this disease group.

	Page Number		Page Number
Chagas	66	<i>Toxoplasma gondii</i>	55
Cytomegalovirus Dried Blood Spots	18	Cytomegalovirus Non-Blood	67

DRUG RESISTANCE

The ability of microorganisms to adapt and develop resistance to antimicrobials is natural and an evolutionary trait they have been employing for thousands of years. Hence there are many examples of drug resistant strains in viral, bacterial and parasitic diseases. However, it is well recognised that the over prescription of antimicrobials within clinical practice and their overuse in domestic products has helped to accelerate drug resistance and led to the emergence of multidrug resistance.

QCMD has established a range of Drug Resistance EQA schemes covering a variety of pathogen types. The primary aims of these schemes are to assess the laboratory in their ability to detect and determine the presence of drug resistance at the molecular level. In addition, some of the schemes also cover drug resistance interpretation.

	Page Number		Page Number
CMV Drug Resistance	17	HIV-1 Drug Resistance	29
Extended Spectrum β -lactamase and Carbapenemase	46	HIV-1 Drug Resistance (Integrase)	29
HBV Drug Resistance	21	Methicillin Resistant <i>Staphylococcus aureus</i>	49
HCV Drug Resistance	23	<i>Mycobacterium tuberculosis</i> Drug Resistance	50
Herpes simplex virus Drug Resistance	27	Vancomycin Resistant Enterococci	52

EXOTIC/EMERGING DISEASES

A complex relationship exists between pathogen genetics, host and the environment. As a result, predicting the future emergence of exotic diseases is difficult. However, globalisation coupled with rapid increases in human populations over the last 50 years has played an important role. Local environmental changes such as deforestation due to urbanisation bring humans into closer contact with potential new pathogen vectors. These factors disturb the subtle balance between pathogen, host and the environment and create the opportunity for the emergence of new disease pathogens or the re-emergence of existing pathogens. These diseases can be caused by newly identified pathogens, pathogen strains such as SARS or the mutation of existing strains such as Influenza virus. In addition, the spread of known pathogens (e.g. West Nile virus & dengue virus) into new geographical areas leading to new potential endemics account for a large number of exotic / emerging diseases. The EQAs within this group focus on those emerging diseases that are frequently being identified within progressive geographic regions.

	Page Number		Page Number
Arthropod-borne viruses	56	MERS coronavirus	36
Babesia	64	Poxviruses	72
Chagas	66	Respiratory I Plus	59
Chikungunya virus	16	SARS-CoV-2	39
Dengue virus	19	West Nile virus	40
Francisella tularensis	68	Yellow fever virus	41
Malaria	71	Zika Virus	41

GASTROINTESTINAL DISEASES

Gastroenteritis can be caused by a wide variety of bacteria, viruses and parasites. It is often associated with severe inflammation of the gastrointestinal tract involving both the stomach and small intestine. This results in acute diarrhoea and vomiting.

Diagnosis is primarily based on clinical symptoms but laboratory diagnosis on the etiological cause is often needed in order to support patient care. In recent years molecular diagnostic techniques such as real-time PCR have also been introduced for the laboratory diagnosis of gastroenteritis, including the ability to simultaneously screen for a wide range of enteric pathogens using multiplex assays. As a result, molecular diagnostic techniques are increasingly being used in the routine laboratory setting for detection, determination and surveillance of a wide range of enteric pathogens.

The general aim of this group of EQA schemes is to allow laboratories to assess their ability in the use of molecular diagnostic tests for a range of viral, bacterial and parasitic enteric pathogens.

	Page Number		Page Number
Adenovirus	15	Helicobacter pylori	47
Bacterial Gastroenteritis	56	Norovirus	36
Clostridium difficile	45	Parasitic Gastroenteritis	58
Diarrheagenic Escherichia coli	46	Viral Gastroenteritis	63

IMMUNOCOMPROMISED ASSOCIATED DISEASES

The treatment and management of patients with compromised immune systems has seen important developments in recent years with, for example, the introduction of novel multi-drug treatment regimes. As a result, the healthcare and management of immunocompromised patients has greatly improved. However, pathogen infection or viral reactivation remain significant contributors to morbidity and mortality in these patients.

A number of opportunistic parasitic, fungal and viral pathogens are of concern in the management of immunocompromised patients due to both acute infection and reactivation of latent virus in the immunocompromised host.

Advances in molecular diagnostics have allowed accurate pathogen assessment and quantitative monitoring, particularly of viral activity over time, which allows early and accurate pre-emptive intervention and management of antiviral drug therapy.

The range of QCMD EQA schemes within this area focus on pathogens known to play a significant clinical role in the management of immunocompromised patients. The general aim of this group of EQA schemes is to assess the ability of laboratories in the detection of the selected pathogen and where appropriate quantitative estimation is also evaluated.

	Page Number		Page Number
<i>Aspergillus spp.</i>	53	Epstein-Barr virus	20
Babesia	64	Epstein-Barr virus Whole Blood	21
BK virus	16	Human cytomegalovirus	30
<i>Candida auris</i>	65	Human herpes virus 6	31
<i>Candida spp.</i>	53	JC virus	35
Chagas	66	<i>Pneumocystis jirovecii</i> pneumonia (PCP)	54
CMV Drug Resistance	17	Torque teno virus	39
CMV Non-Blood	67	<i>Toxoplasma gondii</i>	55
Cytomegalovirus Whole Blood	18	Transplantation (viral)	62

MULTIPLE PATHOGEN/SYNDROMIC

Multiplex based molecular diagnostic tests offer the ability for the detection of a wide range of pathogens within a single diagnostic test.

Syndromic approaches to test respiratory, gastroenteritis and meningitis infections allows clinicians to identify the cause of infection from a wide range of pathogens often in a near patient, point of impact setting where rapid diagnosis aids faster clinical decision making and patient treatment. These technologies are generally used as a screening approach where identification of pathogens allow improved patient management at initial point of contact.

QCMD have introduced multi-pathogen/syndromic schemes to address this growing need in the clinical setting. A range of schemes cover respiratory infections, transplant associated infections, central nervous system infections, sexually transmitted infections and gastroenteritis infections caused by a range of aetiologies.

	Page Number		Page Number
Arthropod-borne viruses	56	Respiratory I plus	59
Bacterial Gastroenteritis	56	Respiratory II	60
Central Nervous System I (Viral Meningitis and Encephalitis)	57	Respiratory III	60
Central Nervous System II (Non-Viral Meningitis and Encephalitis)	57	Sepsis	61
<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoea</i>	44	Sexually Transmitted Infections I	61
MALDI-TOF	58	Sexually Transmitted Infections II	62
Parasitic Gastroenteritis	58	Transplantation (viral)	62
Respiratory I	59	Viral Gastroenteritis	63

RESPIRATORY DISEASES

Respiratory tract infections (RTIs) are common conditions, experienced by most adults and children each year. They can affect both the upper and lower respiratory tract and range from the common cold to viral and bacterial pneumonia. For the young, the elderly and the immune compromised, RTIs can be a significant health threat if not managed effectively.

RTIs can be caused by a large number of bacterial, viral and fungal pathogens which have nearly indistinguishable physiological symptoms. This can increase the chances of undiagnosed or misdiagnosed infections leading to patients either not receiving critical medications, or receiving unnecessary antibiotics. The advance of molecular diagnostic techniques has improved our ability to rapidly determine the causative agents of RTIs and has the potential to improve patient management, control of nosocomial transmission and promote targeted therapy.

The Respiratory EQA schemes cover 17 of the major viral, bacterial and fungal causes of RTIs, focusing on the pathogen load and allowing assessment of the laboratories ability to accurately identify the species of interest at clinically relevant levels.

	Page Number		Page Number
Adenovirus	15	<i>Mycobacterium tuberculosis</i>	49
Atypical mycobacterium	42	<i>Mycobacterium tuberculosis</i> Drug Resistance	50
<i>Bordetella pertussis</i>	43	<i>Mycoplasma pneumoniae</i>	51
<i>Chlamydia psittaci</i>	44	Parainfluenza virus	37
<i>Chlamydophila pneumoniae</i>	45	<i>Pneumocystis jirovecii</i> pneumonia (PCP)	54
Coronavirus	17	Respiratory I	59
Group A Streptococcus	69	Respiratory I plus	59
Human metapneumovirus	31	Respiratory II	60
Influenza A & B virus	34	Respiratory III	60
Influenza Typing	34	Respiratory syncytial virus	38
<i>Legionella</i> spp.	48	Rhinovirus	38
Measles / Mumps	35	SARS-CoV-2	39
MERS coronavirus	36		

SEXUALLY TRANSMITTED INFECTIONS

Sexually transmitted infections (STIs) remain a major public health concern throughout the world with some infections reaching epidemic proportions in sexually active groups. As a result, a number of WHO and UN global strategies have been initiated in an attempt to control the spread of STIs.

STIs are the main preventable cause of infertility, particularly in women. However, some STIs remain asymptomatic before leading to serious reproductive complications and congenital infections, therefore appropriate diagnosis and treatment is essential.

Molecular diagnostic assays allow the accurate assessment of STIs in patients that present with similar symptoms or asymptomatic persons from at risk groups allowing early and accurate intervention and treatment.

The range of QCMD EQA schemes within this area focus on pathogens known to be the most common cause of STIs. The general aim of this group of EQA schemes is to assess the ability of laboratories in the detection of the selected pathogen.

	Page Number		Page Number
<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>	44	<i>Mycoplasma Genitalium</i>	61
Herpes simplex virus 1 & 2	27	Sexually Transmitted Infections I	61
Herpes simplex virus Drug Resistance	27	Sexually Transmitted Infections II	62
Human Papillomavirus (PreservCyt)	32	Syphilis	51
Human Papillomavirus (SurePath)	33	<i>Trichomonas vaginalis</i>	55

TRANSPLANT ASSOCIATED DISEASES

Advances in transplant medicine, including the development of immunosuppressive agents, has greatly improved the prospects of transplant recipients. However, pathogen infection and in particular viral reactivation remain significant contributors to transplant patient morbidity and mortality.

A number of viruses are of particular concern, these include: human herpes virus6 (HHV6), human cytomegalovirus (CMV) and Epstein-Barr virus (EBV) along with human adenovirus (ADV), JC virus (JCV) and BK virus (BKV). Other opportunistic infections such as the parasite *Toxoplasma gondii* are also relevant. Advances in molecular diagnostics have allowed accurate pathogen assessment prior to transplant and accurate quantitative monitoring, particularly of viral activity over time, after the transplant has been performed. This in turn allows early and accurate pre-emptive intervention and antiviral drug therapy.

The range of QCMD EQA schemes within this area focus on those pathogens known to play a significant clinical role in transplant medicine. The general aim of this group of EQA schemes is to assess the ability of laboratories in the detection of the selected pathogen and where appropriate quantitative estimation is also evaluated.

	Page Number		Page Number
Adenovirus	15	Human cytomegalovirus	30
BK virus	16	Human herpes virus 6	31
CMV Drug Resistance	17	JC virus	35
Cytomegalovirus Non-Blood	67	Torque teno virus	39
Cytomegalovirus Whole Blood	18	<i>Toxoplasma gondii</i>	55
Epstein-Barr virus	20	Transplantation (viral)	62
Epstein-Barr virus Whole Blood	21		

EQA GROUPS

TYPING

Advances in the treatment and management of patient infection have seen important developments in recent years. In particular the introduction of novel antiviral drug therapies has improved the medium and long- term prospects of infected patients. However, the development of drug resistant pathogens is an increasing complication and remains a significant factor in the treatment of these patient groups.

The use of genotyping and sequencing technologies has allowed accurate pathogen assessment and monitoring of patient samples over time. This allows early and accurate determination of pathogen status. Which in turn allows pre-emptive intervention and management of antiviral drug therapy.

The range of QCMD EQA schemes within this area focus on pathogens known to play a significant clinical role in the management of infection. The general aim of this group of EQA schemes is to assess the ability of laboratories in the genetic determination of the selected pathogen and where appropriate the specific mutation points within the target gene.

	Page Number		Page Number
Bacterial 16S Ribosomal RNA	42	Herpes simplex virus Drug Resistance	27
CMV Drug Resistance	17	HIV-1 Drug Resistance	29
Enterovirus Typing	20	HIV-1 Drug Resistance (Integrase)	29
HBV Drug Resistance	21	Influenza Typing	34
HBV Genotyping	22	MALDI-TOF	58
HCV Drug Resistance	23	Methicillin Resistant <i>Staphylococcus aureus</i> Typing (epidemiology and outbreak studies)	48
HCV Genotyping	24		

OTHER

QCMD are continuously expanding our range of EQA schemes, some of which are outside the defined EQA groups listed above

	Page Number		Page Number
Dermatophytosis	54	Joint Infection	70
Group B Streptococcus	47	Viral Metagenomics NGS	72

VIRAL EQA

ADENOVIRUS

ADVDNA25 - QAV054133

To assess the proficiency of laboratories in the detection and quantitation of adenovirus.

To assess the proficiency of laboratories in the detection of different adenovirus serotypes including currently circulating serotypes of interest.

Feature	Available format(s)	
Catalogue Number	QAV054133_1	QAV054133_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium and/or Plasma	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Condition	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

B19 VIRUS

B19DNA25 - QAV034116

To assess the proficiency of laboratories in detection and quantitation of B19 virus.

Feature	Available format(s)	
Catalogue Number	QAV034116_1	QAV034116_2
Total Number of Challenges	1	2
Number of Panel Members	8	4
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Clinical material	
Matrix Panel Format	Plasma	
Units of Measurement	The primary unit is IU/ml however other units will be accepted	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.2 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

BK VIRUS

BKDNA25 - QAV144166

To assess the proficiency of laboratories molecular assays in detecting various types and concentrations of BK virus (BKV). To assess the proficiency of laboratories in the reliable quantitation of BKV viral load.

Feature	Available format(s)	
Catalogue Number	QAV144166_1	QAV144166_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium and/or Plasma and/or Urine	
Units of Measurement	The primary unit is IU/ml however other units will be accepted	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

CHIKUNGUNYA VIRUS

CHIKV25 - QAV154175

To assess the laboratory's ability to detect chikungunya virus using their routine molecular diagnostic platform and procedures.

Feature	Available format(s)
Catalogue Number	QAV154175_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

CMV DRUG RESISTANCE

CMVDR25-QAV144169

To assess the laboratories' ability to detect CMV drug resistance mutations in kinase UL97, polymerase UL54 gene and the UL56 that forms part of the terminase, using sequencing techniques.

Feature	Available format(s)
Catalogue Number	QAV144169_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma and/or Physiological Buffer
Panel Member Target Range	Various mutations - kinase (UL97), polymerase (UL54) and terminase (UL56) genes
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Sequence Analysis
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Condition	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

CORONAVIRUS

CVRNA25 - QAV064137

To assess the proficiency of laboratories in the detection of coronavirus. To assess the proficiency of laboratories in the detection of different coronavirus genotypes.

Feature	Available format(s)
Catalogue Number	QAV064137_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering Clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

CYTOMEGALOVIRUS DRIED BLOOD SPOTS

CMVDBS25 - QAV064127

To assess the performance of laboratories in the detection of clinically relevant levels of human cytomegalovirus (CMV) from dried blood spots.

Feature	Available format(s)
Catalogue Number	QAV064127_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3

Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Dried Blood Spots
Units of Measurement	The primary unit is IU/ml however other units will be accepted
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	2x50µl
Panel Sample Pre-treatment Requirement	Extraction from dried blood spot
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

CYTOMEGALOVIRUS WHOLE BLOOD

CMVWB25 - QAV124150

To evaluate the ability of laboratories in the detection of CMV from whole blood samples. To assess the precision of molecular assays at clinically relevant viral loads.

Feature	Available format(s)	
Catalogue Number	QAV124150_1	QAV124150_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Whole Blood	
Units of Measurement	The primary unit is IU/ml however other units will be accepted	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-30°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

DENGUE VIRUS

DENVRNA25 - QAV114148

To assess the proficiency of laboratories in the detection of dengue virus. To assess the proficiency of laboratories in distinguishing dengue virus from other flaviviruses.

Feature	Available format(s)
Catalogue Number	QAV114148_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

ENTEROVIRUS

EVRNA25 - QAV984104

To assess the ability of laboratories molecular assays to detect different types and concentrations of enterovirus (EV). To review the performance of laboratories quantitative EV molecular assays.

Feature	Available format(s)	
Catalogue Number	QAV984104_1	QAV984104_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured virus and/or Clinical material	
Matrix Panel Format	Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative. Quantitative for information purposes only	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

ENTEROVIRUS TYPING

EVTP25 - QAV164185

To assess laboratories ability to correctly identify specific enterovirus types using their routine molecular method and procedures.

Feature	Available format(s)
Catalogue Number	QAV164185_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q1
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering Clinical range
Panel Member Sample Volume	1.0ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

EPSTEIN-BARR VIRUS

EBVDNA25 - QAV024121

To assess the proficiency of laboratories in the detection and quantitation of Epstein-Barr virus (EBV).

Feature	Available format(s)	
Catalogue Number	QAV024121_1	QAV024121_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium and/or Plasma	
Units of Measurement	The primary unit is IU/ml however other units will be accepted	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

EPSTEIN-BARR VIRUS WHOLE BLOOD

EBVWB25 - QAV134161

To assess the proficiency of laboratories in the detection and quantitation of Epstein-Barr virus (EBV) in whole blood samples.

Feature	Available format(s)	
Catalogue Number	QAV134161_1	QAV134161_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Whole Blood	
Units of Measurement	The primary unit is IU/ml however other units will be accepted	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-30°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

HBV DRUG RESISTANCE

HBVDR25 - QAV124160

To assess the performance of laboratories in the detection of drug resistance mutations in the hepatitis B virus (HBV) DNA polymerase gene using sequencing techniques and/or LiPA technology.

Feature	Available format(s)
Catalogue Number	QAV124160_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma
Panel Member Target Range	Various mutations – DNA polymerase
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Sequence Analysis
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HBV GENOTYPING

HBVGT25 - QAV064118

To assess the proficiency of laboratories in the correct genotyping of hepatitis B virus (HBV) using molecular methods.

Feature	Available format(s)
Catalogue Number	QAV064118_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q1
Specifications	
Sample NA Target Source	Clinical material
Genotypic Variant	Various HBV genotypes
Matrix Panel Format	Plasma
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.2 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HCV DRUG RESISTANCE

HCVDR25 - QAV134167

The QCMD HCV Drug Resistance (HCVDR) scheme has to-date been based around resistance to the first-generation Direct Acting Antiviral (DAA) NS3 protease inhibitors, boceprevir and telaprevir, which became widely available circa 2011. However the "previr" family of drugs are only effective against HCV genotype 1 infections limiting the scope of the HCVDR scheme to single genotype, single gene target. First generation DAAs were supplemented in 2014 with the release of the first "buvir" NS5b inhibitors for use against genotype 1 followed by the release of the first NS5a inhibitor "asvir" family of drugs in 2015, which are effective against both genotype 1 and 3 infections.

All three drug families are now in routine use and are included in both the WHO list of essential medicines and the national guidelines of several countries for treatment of HCV. Based on this the HCVDR scheme has been updated to reflect the current clinical environment with regards to drug resistance testing.

The aim of the HCVDR EQA is to assess the performance of laboratories in the detection of drug resistance mutations in the hepatitis C virus (HCV) genotypes 1 and 3 (NS3 and NS5 regions) using sequencing techniques.

Feature	Available format(s)
Catalogue Number	QAV134167_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma
Panel Member Target Range	Various mutations – NS3 and NS5a regions
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Sequence Analysis
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HCV GENOTYPING

HCVGT25 - QAV034117

To assess the proficiency of laboratories in the correct genotyping of hepatitis C virus (HCV) using molecular methods.

Feature	Available format(s)
Catalogue Number	QAV034117_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q1
Specifications	
Sample NA Target Source	Clinical material
Genotypic Variant	Various HCV genotypes and subtypes
Matrix Panel Format	Plasma
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.2 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HEPATITIS A VIRUS

HAVRNA25 - QAV124156

To evaluate the ability of laboratories in the molecular detection of hepatitis A virus (HAV) in terms of sensitivity and specificity.

Feature	Available format(s)
Catalogue Number	QAV124156_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q1
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.2 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HEPATITIS B VIRUS

HBVDNA25 - QAV994110

To assess the proficiency of laboratories in the detection and quantitation of hepatitis B virus (HBV). To assess the proficiency of laboratories is the detection and quantitation of different HBV genotypes.

Feature	Available format(s)		
Catalogue Number	QAV994110_1	QAV994110_2	QAV994110_4
Total Number of Challenges	1	2	4
Number of Panel Members	8	4	4
Distribution / Testing Period	Q3	Q1 & Q3	Q1, Q2, Q3 & Q4
Specifications			
Sample NA Target Source	Cultured virus and/or Clinical material		
Matrix Panel Format	Plasma		
Units of Measurement	The primary unit is IU/ml however other units will be accepted		
Panel Member Target Range	Covering clinical range		
Panel Member Sample Volume	1.2 ml		
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly		
Panel Analysis type	Qualitative & Quantitative		
Panel Testing	Evaluated by various molecular methodologies		
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice		
Accreditation/Regulatory Status	Accredited to ISO17043		

HEPATITIS C VIRUS

HCVRNA25 - QAV994112

To assess the proficiency of laboratories in the detection and quantitation of hepatitis C virus (HCV) RNA. To assess the proficiency of laboratories in the detection and quantitation of different HCV genotypes.

Feature	Available format(s)		
Catalogue Number	QAV994112_1	QAV994112_2	QAV994112_4
Total Number of Challenges	1	2	4
Number of Panel Members	8	4	4
Distribution / Testing Period	Q3	Q1 & Q3	Q1, Q2, Q3 & Q4
Specifications			
Sample NA Target Source	Clinical material		
Matrix Panel Format	Plasma		
Units of Measurement	The primary unit is IU/ml however other units will be accepted		
Panel Member Target Range	Covering clinical range		
Panel Member Sample Volume	1.2 ml		
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly		
Panel Analysis type	Qualitative & Quantitative		
Panel Testing	Evaluated by various molecular methodologies		
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice		
Accreditation/Regulatory Status	Accredited to ISO17043		

HEPATITIS D VIRUS

HDV25 - QAV144170

To evaluate laboratories in the detection of HDV within the routine clinical setting.

Feature	Available format(s)
Catalogue Number	QAV144170_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q4
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma
Units of Measurement	The primary unit is IU/ml however other units will be accepted
Panel Member Target Range	Covering clinical range
Panel Analysis type	Qualitative & Quantitative
Panel Member Sample Volume	1.2 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HEPATITIS E VIRUS

HEVRNA25 - QAV124157

To evaluate the ability of laboratories in the detection and quantification of hepatitis E virus (HEV).

Feature	Available format(s)
Catalogue Number	QAV124157_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q4
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma
Panel Member Target Range	Covering Clinical range
Panel Member Sample Volume	0.6 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative & Quantitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HERPES SIMPLEX VIRUS 1 & 2

HSVDNA25 - QAV994105

To assess the ability of laboratories molecular assays to detect different types and concentrations of herpes simplex virus (HSV). To review the performance of laboratories quantitative HSV molecular assays.

Feature	Available format(s)	
Catalogue Number	QAV994105_1	QAV994105_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured virus and/or Clinical material	
Matrix Panel Format	Transport medium and/or synthetic CSF	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative. Quantitative for information purposes only	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

HERPES SIMPLEX VIRUS DRUG RESISTANCE

HSVDR25 - QAV164184

To assess the performance of laboratories in the detection of drug resistance mutations in the herpes simplex virus thymidine kinase (UL23) and DNA polymerase (UL30) genes using sequencing techniques.

Feature	Available format(s)
Catalogue Number	QAV164184_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q1
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Various mutations - Thymidine Kinase (UL23) and DNA polymerase (UL30)
Panel Member Sample Volume	1.0ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Sequence Analysis
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HIV-1 (DNA)

HIVDNA25 - QAV034114

To assess the proficiency of laboratories in the detection of human immunodeficiency virus type 1 (HIV-1) pro-viral DNA.

Feature	Available format(s)	
Catalogue Number	QAV034114_1	QAV034114_2
Total Number of Challenges	1	2
Number of Panel Members	8	4
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured proviral cells	
Matrix Panel Format	Physiological Buffer	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	0.2 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative. Quantitative for information purposes only	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

HIV-1 (RNA)

HIVRNA25 - QAV994108

To assess the proficiency of laboratories in detection and quantitation of human immunodeficiency virus (HIV) RNA. To assess the proficiency of laboratories in detection and quantitation of different HIV genotypes.

Feature	Available format(s)		
Catalogue Number	QAV994108_1	QAV994108_2	QAV994108_4
Total Number of Challenges	1	2	4
Number of Panel Members	8	4	4
Distribution / Testing Period	Q3	Q1 & Q3	Q1, Q2, Q3 & Q4
Specifications			
Sample NA Target Source	Cultured virus and/or Clinical material		
Matrix Panel Format	Plasma		
Units of Measurement	The primary unit is IU/ml however other units will be accepted		
Panel Member Target Range	Covering clinical range		
Panel Member Sample Volume	1.2 ml		
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly		
Panel Analysis type	Qualitative & Quantitative		
Panel Testing	Evaluated by various molecular methodologies		
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice		
Accreditation/Regulatory Status	Accredited to ISO17043		

HIV-1 DRUG RESISTANCE

HIVDR25 - QAV024131

To assess the performance of laboratories in the detection of drug resistance mutations in the HIV-1 protease and reverse transcriptase genes.

Feature	Available format(s)
Catalogue Number	QAV024131_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q4
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma
Panel Member Target Range	Various mutations - reverse transcriptase (RT) and protease (PR) genes
Panel Member Sample Volume	1.0ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Sequence Analysis
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HIV-1 DRUG RESISTANCE (INTEGRASE)

HIVDRint25 - QAV114146

To assess the performance of laboratories in the detection of drug resistance mutations in the HIV-1 integrase gene using sequencing techniques.

Feature	Available format(s)
Catalogue Number	QAV114146_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q4
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma
Panel Member Target Range	Various mutations - integrase (INT) gene
Panel Member Sample Volume	1.0ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Sequence Analysis
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HIV-2

HIV2_25 - QAV204212

To assess the proficiency of laboratories in the detection and quantitation of human immunodeficiency virus type2 (HIV-2).

Feature	Available format(s)
Catalogue Number	QAV204212_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured material and/or Clinical material
Matrix Panel Format	Plasma
Units of Measurement	The primary unit is IU/ml however other units will be accepted
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.2ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HUMAN CYTOMEGALOVIRUS

CMVDNA25 - QAV014120

To assess the proficiency of laboratories in the detection and quantitation of human cytomegalovirus (CMV)

Feature	Available format(s)	
Catalogue Number	QAV014120_1	QAV014120_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Plasma	
Units of Measurement	The primary unit is IU/ml however other units will be accepted	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

HUMAN HERPES VIRUS 6

HHV6DNA25 - QAV084119

To assess the proficiency of laboratories' molecular assays in the detection of various types of human herpes virus 6 (HHV6). To assess the proficiency of laboratories in the reliable quantitation of HHV6 viral load.

Feature	Available format(s)	
Catalogue Number	QAV084119_1	QAV084119_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Genotypic Variant	Subtypes A and B	
Matrix Panel Format	Transport Medium and/or Plasma	
Units of Measurement	The primary unit is IU/ml however other units will be accepted	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

HUMAN METAPNEUMOVIRUS

MPV25 - QAV054135

To assess the sensitivity and specificity of laboratories in the detection of human metapneumovirus (MPV). To assess the ability of laboratories in the detection of different human MPV types.

Feature	Available format(s)
Catalogue Number	QAV054135_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HUMAN PAPILLOMAVIRUS (PRESERVCYT)

HPVPRES25 - QAV094130

Human Papillomavirus (HPV) infection has been detected in over 95% of cervical cancers. The second most common cancer detected in females worldwide. The detection of HPV infection is an important part of the triage, with cytomorphological examination in the early detection of cervical cancer in scrapings. For effective triage, quantitative detection and accurate HPV-typing at clinically relevant levels is essential. The introduction of nucleic acid amplification technologies (NAT) and nucleic acid hybridisation assays has led to the development of sensitive, type specific diagnostic tests that can rapidly identify HPV infection. As a result, these tests are now of great practical and clinical relevance. The aim of the EQA is to assess the proficiency of laboratories in the detection of different high risk Human Papillomavirus types within a PreservCyt matrix.

Feature	Available format(s)	
Catalogue Number	QAV094130_1	QAV094130_2
Total Number of Challenges	1	2
Number of Panel Members	12	6
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Clinical material and/or cell lines containing HPV	
Matrix Panel Format	Transport Medium (PreservCyt)	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	4.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	15-30°C / Liquid Ambient	
Accreditation/Regulatory Status	Accredited to ISO17043	

HUMAN PAPILLOMAVIRUS (SUREPATH)

HPVSURE25 - QAV184204

Human Papillomavirus (HPV) infection has been detected in over 95% of cervical cancers, the second most common cancer detected in females worldwide. The detection of HPV infections is an important part of the triage with cytomorphological examination in the early detection of cervical cancer in scrapings. For effective triage, quantitative detection and accurate HPV- typing at clinically relevant levels is essential. The introduction of nucleic acid amplification technologies (NAT) and nucleic acid hybridisation assays has led to the development of sensitive, type specific diagnostic tests that can rapidly identify HPV infection. As a result, these tests are now of great practical and clinical relevance.

To assess the proficiency of laboratories in the detection of different high risk Human Papillomavirus types within a SurePath™ matrix.

Feature	Available format(s)
Catalogue Number	QAV184204_1
Total Number of Challenges	1
Number of Panel Members	12
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Clinical material and/or cell lines containing HPV
Matrix Panel Format	Transport Medium (SurePath)
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

INFLUENZA A & B VIRUS

INFRNA25 - QAV054134

To assess the proficiency of laboratories in detection of influenza virus RNA.

To assess the proficiency of laboratories in distinguishing influenza virus A and B.

Feature	Available format(s)	
Catalogue Number	QAV054134_1	QAV054134_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

INFLUENZA TYPING

INFTP25 - QAV064138

To assess the proficiency of laboratories in the detection of different influenza virus types, subtypes and lineages To assess the proficiency of laboratories in the typing and subtyping/lineage determination of influenza viruses.

Feature	Available format(s)
Catalogue Number	QAV064138_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q4
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

JC VIRUS

JCDNA25 - QAV074106

To assess the proficiency of laboratories molecular assays in detecting various types and concentrations of JC virus (JCV). To assess the proficiency of laboratories in the reliable quantitation of JCV viral load.

Feature	Available format(s)	
Catalogue Number	QAV074106_1	QAV074106_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium and/or Plasma	
Units of Measurement	The primary unit is IU/ml however other units will be accepted	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative & Quantitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

MEASLES / MUMPS

MM25 - QAV144171

To assess the proficiency of laboratories in the detection of mumps and/or measles using routine molecular methods.

Feature	Available format(s)
Catalogue Number	QAV144171_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

MERS CORONAVIRUS

MERS25 - QAV154181

To assess the proficiency of laboratories molecular technologies for the detection and determination of MERS-CoV from other coronaviruses.

Feature	Available format(s)
Catalogue Number	QAV154181_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering Clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

NOROVIRUS

NVRNA25 - QAV084139

To assess the specificity and sensitivity of laboratories in the detection of norovirus. To assess the ability of the laboratories to detect different norovirus genogroups.

Feature	Available format(s)	
Catalogue Number	QAV084139_1	QAV084139_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium and/or Physiological Buffer and/or Synthetic Faecal Matrix	
Panel Member Sample Volume	1.0 ml VTm, 0.1 ml Buffer	
Panel Sample Pre-treatment Requirement	NA samples are ready for analysis. Pre-treatment may be needed for SFM. Follow manufacturers IFU	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

PARAINFLUENZA VIRUS

PINFRNA25 - QAV064136

To assess the proficiency of laboratories in the detection of parainfluenza virus.

To assess the proficiency of laboratories in the detection of different parainfluenza virus types.

Feature	Available format(s)
Catalogue Number	QAV064136_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering Clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

PARECHOVIRUS

PEVRNA25 - QAV114145

To assess the ability of laboratories molecular assays to detect different types and concentrations of parechovirus.

Feature	Available format(s)	
Catalogue Number	QAV114145_1	QAV114145_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured virus and/or Clinical material	
Matrix Panel Format	Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

RESPIRATORY SYNCYTIAL VIRUS

RSV25 - QAV054142

To assess the specificity and sensitivity of laboratories in the detection of respiratory syncytial virus (RSV) by NAT. To assess the ability of laboratories in the detection of different RSV types by NAT.

Feature	Available format(s)	
Catalogue Number	QAV054142_1	QAV054142_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

RHINOVIRUS

RVRNA25 - QAV064143

To assess the proficiency of laboratories in the detection of rhinovirus.
To assess the proficiency of laboratories in the detection of different rhinovirus genotypes

Feature	Available format(s)
Catalogue Number	QAV064143_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

SARS-COV-2

SCV2_25 - QAV204215

To assess the proficiency of laboratories in the detection of the new variant SARS-CoV-2 coronavirus including variants of concern (VOC). To assess the proficiency of laboratories in the differentiation of different coronavirus genotypes.

Feature	Available format(s)			
Catalogue Number	QAV204215_1A	QAV204215_1B	QAV204215_1C	QAV204215_1D
Total Number of Challenges	1	1	1	1
Number of Panel Members	5	5	5	5
Distribution / Testing Period	Q1	Q2	Q3	Q4
Specifications				
Sample NA Target Source	Cultured and/or Clinical material			
Matrix Panel Format	Transport Medium			
Panel Member Target Range	Covering clinical range			
Panel Member Sample Volume	1.0 ml			
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly			
Panel Analysis type	Qualitative			
Panel Testing	Evaluated by various molecular methodologies			
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice			
Accreditation/Regulatory Status	Accredited to ISO17043			

TORQUE TENO VIRUS

TTV25 - QAV184203

The aim of the Torque Teno Virus (TTV) EQA is to assess laboratories ability to detect TTV using routine molecular diagnostic platform and procedures.

Feature	Available format(s)
Catalogue Number	QAV184203_1
Total Number of Challenges	1
Number of Panel Members	6
Distribution / Testing Period	Q4
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

VARICELLA-ZOSTER VIRUS

VZVDNA25 - QAV034103

To assess the ability of laboratories molecular assays to detect different concentrations of Varicella-Zoster virus (VZV). To review the performance of laboratories quantitative VZV molecular assays.

Feature	Available format(s)	
Catalogue Number	QAV034103_1	QAV034103_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured virus and/or Clinical material	
Matrix Panel Format	Transport medium and/or Synthetic CSF	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative. Quantitative for information purposes only	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

WEST NILE VIRUS

WNVRNA25 - QAV104141

To assess the proficiency of laboratories in the detection of West Nile virus.
To determine the proficiency of laboratories in distinguishing West Nile virus from other flaviviruses.

Feature	Available format(s)
Catalogue Number	QAV104141_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

YELLOW FEVER VIRUS

YFV25 - QAV194207

To assess the proficiency of laboratories in the detection of yellow fever virus.

To determine the proficiency of laboratories in distinguishing yellow fever virus from other flaviviruses.

Feature	Available format(s)
Catalogue Number	QAV194207_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

ZIKA VIRUS

ZIKA25 - QAV164186

To assess the proficiency of laboratories in the detection of Zika virus and determine the proficiency of laboratories in distinguishing Zika virus from other flaviviruses.

Feature	Available format(s)
Catalogue Number	QAV164186_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL EQA

ATYPICAL MYCOBACTERIUM

NTM25 - QAB194208

To assess the proficiency of laboratories to detect atypical mycobacterium or non-tuberculous mycobacteria (NTM).

Feature	Available format(s)
Catalogue Number	QAB194208_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q1
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Synthetic Sputum and/or Transport Medium and/or Physiological Buffer
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Pre-treatment not generally required - follow test manufacturers IFU
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Liquid Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL 16S RIBOSOMAL RNA

B16SrRNA25 - QAB164183

To assess the proficiency of laboratories to detect, identify and interpret which bacterial species are provided within each panel member using their routine 16S rRNA molecular diagnostic procedures.

Feature	Available format(s)
Catalogue Number	QAB164183_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Physiological Buffer
Panel Member Target Range	Covering Clinical range
Panel Member Sample Volume	0.5 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

BORDETELLA PERTUSSIS

BPDNA25 - QAB094132

To assess the proficiency of laboratories in the detection of *Bordetella pertussis*.

Feature	Available format(s)
Catalogue Number	QAB094132_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Physiological Buffer
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

BORRELIA BURGDORFERI SPP. (LYME DISEASE)

BbDNA25 - QAB114147

To assess the qualitative detection of *B. burgdorferi* sensu lato genospecies complex at different concentrations.

Feature	Available format(s)
Catalogue Number	QAB114147_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Microbiological Medium and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL EQA

CHLAMYDIA PSITTACI

CPS25 - QAB134165

To assess the laboratories ability in the molecular detection of *Chlamydia psittaci*.

Feature	Available format(s)
Catalogue Number	QAB134165_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE

CTNG25 - QAB174191

To assess proficiency of laboratories in the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* using molecular technologies.

Feature	Available format(s)	
Catalogue Number	QAB174191_1	QAB174191_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured bacteria and/or Clinical material	
Matrix Panel Format	Urine and/or Physiological Buffer and/or Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	4.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

BACTERIAL EQA

CHLAMYDOPHILA PNEUMONIAE

CP25 - QAB084107

To assess the proficiency of laboratories in the correct detection of *Chlamydomphila pneumoniae*.

Feature	Available format(s)
Catalogue Number	QAB084107_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Bronchoalveolar Lavage (BAL) and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	0.5 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

CLOSTRIDIUM DIFFICILE

CDDNA25 - QAB084125

A terminology update in the Clostridium field has introduced a name change from *Clostridium difficile* to *Clostridioides difficile* this has been adopted by the European Study Group for *Clostridium difficile*. Please note that QCMD will however continue to refer to this scheme and associated pathogens as *Clostridium difficile* at this time.

To assess the proficiency of laboratories in the molecular detection of *Clostridium difficile*.

Feature	Available format(s)	
Catalogue Number	QAB084125_1	QAB084125_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Microbiological Medium and/or Synthetic Faecal Matrix	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Pre-treatment may be required for SFM. Follow test manufacturers IFU	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

BACTERIAL EQA

DIARRHEAGENIC ESCHERICHIA COLI

E.COLI25 - QAB154179

To assess laboratories ability to detect diarrheagenic *E. coli* strains using their routine molecular diagnostic platform and procedures.

Feature	Available format(s)
Catalogue Number	QAB154179_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Synthetic Faecal Matrix and/or Physiological Buffer and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Pre-treatment may be required for SFM. Follow test manufacturers IFU
Panel Analysis type	Molecular Typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

EXTENDED SPECTRUM β -LACTAMASE AND CARBAPENEMASE

ESBL25 - QAB134162

To assess the laboratories ability to detect β -lactamase and carbapenemase coding genes in a clinical setting using their routine molecular diagnostic procedures.

Feature	Available format(s)
Catalogue Number	QAB134162_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Genotypic Variant	Various drug resistance strains
Matrix Panel Format	Physiological Buffer
Panel Member Sample Volume	0.5 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Pre-treatment may be required for SFM. Follow test manufacturers IFU
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL EQA

GROUP B STREPTOCOCCUS

GBS25 - QAB174200

To assess the laboratories ability in the qualitative detection of group B Streptococcus using their routine molecular diagnostic procedures.

Feature	Available format(s)
Catalogue Number	QAB174200_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q4
Specifications	
Sample NA Target Source	Cultured material and/or Clinical material
Matrix Panel Format	Plasma and/or Synthetic CSF and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

HELICOBACTER PYLORI

H.PYLORI25 - QAB164190

To assess the laboratories ability in the qualitative detection of *H. pylori* and where appropriate, the identification of *H. pylori* antibiotic resistance status using their routine molecular diagnostic procedures.

Feature	Available format(s)
Catalogue Number	QAB164190_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Synthetic Faecal Matrix and/or Physiological Buffer
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Pre-treatment may be required for SFM. Follow test manufacturers IFU
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL EQA

LEGIONELLA SPP.

LPDNA25 - QAB044122

To assess proficiency of laboratories in the detection of *Legionella* species.

Feature	Available format(s)
Catalogue Number	QAB044122_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q1
Specifications	
Sample NA Target Source	Cultured bacteria and/or Clinical material
Matrix Panel Format	Bronchoalveolar lavage (BAL) and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	0.5 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS TYPING (EPIDEMIOLOGY AND OUTBREAK STUDIES)

MRSATP25 - QAB074128



To assess the proficiency of laboratories in the molecular typing for outbreak analysis of Methicillin Resistant *Staphylococcus aureus*.

This EQA scheme is suitable for all molecular methods for typing *Staphylococcus aureus* strains including SPA typing and whole genome sequence analysis, where the type and/or the relationship between isolates can be determined.

Feature	Available format(s)
Catalogue Number	QAB074128_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Microbiological Medium and/or Transport Medium
Panel Member Target Range	Genetic variants of <i>Staphylococcus aureus</i>
Panel Member Sample Volume	0.2 ml
Panel Sample Pre-treatment Requirement	Culture followed by standard NA extraction
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various methodologies
Storage / Shipment Conditions	2-8°C / Liquid Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL EQA

METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS

MRSADNA25 - QAB064124

To assess the performance of laboratories in the detection of Methicillin Resistant *Staphylococcus aureus*.

Feature	Available format(s)
Catalogue Number	QAB064124_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Microbiological Medium and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Liquid Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

MYCOBACTERIUM TUBERCULOSIS

MTBDNA25 - QAB014129

To assess the proficiency of laboratories in the molecular detection of *Mycobacterium tuberculosis* complex.

Feature	Available format(s)	
Catalogue Number	QAB014129_1	QAB014129_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Sputum and/or Synthetic Sputum and/or Synthetic CSF	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Pre-treatment may be required for the sputum samples – follow test manufacturers IFU	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	2-8°C / Liquid Ambient	
Accreditation/Regulatory Status	Accredited to ISO17043	

BACTERIAL EQA

MYCOBACTERIUM TUBERCULOSIS DRUG RESISTANCE

MTBDR25 - QAB194209

To assess the proficiency of laboratories to detect and differentiate MTB drug resistance strains using their routine molecular diagnostic procedures.

Feature	Available format(s)
Catalogue Number	QAB194209_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Genotypic Variant	Various drug resistance strains
Matrix Panel Format	Sputum and/or Synthetic Sputum and/or Synthetic CSF
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Pre-treatment may be required for the sputum samples – follow test manufacturers IFU
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Liquid Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

MYCOPLASMA GENITALIUM

MG25 - QAB184205

To assess the performance of laboratories in the detection of *Mycoplasma genitalium*.

Feature	Available format(s)
Catalogue Number	QAB184205_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured material and/or Clinical material
Matrix Panel Format	Transport medium and/or Urine and/or Physiological Buffer
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	4.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL EQA

MYCOPLASMA PNEUMONIAE

MP25 - QAB174192

To assess the proficiency of laboratories in the correct detection of *Mycoplasma pneumoniae*.

Feature	Available format(s)
Catalogue Number	QAB174192_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Bronchoalveolar Lavage (BAL) and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	0.5 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

SYPHILIS

SYPH25 - QAB154180

To assess laboratories ability to detect *Treponema pallidum* using their routine molecular diagnostic platform and procedures.

Feature	Available format(s)
Catalogue Number	QAB154180_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Urine and/or Physiological Buffer and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL EQA

VANCOMYCIN RESISTANT ENTEROCOCCI

VRE25 - QAB134163

This EQA will focus on the laboratories ability to detect and determine different VRE in clinically relevant sample types using molecular techniques.

Feature	Available format(s)
Catalogue Number	QAB134163_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Genotypic Variant	Various drug resistance strains
Matrix Panel Format	Microbiological Medium and/or Transport Medium
Panel Member Sample Volume	0.5 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Molecular typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

FUNGAL EQA

ASPERGILLUS SPP.

ASPDNA25 - QAF104140

To assess the qualitative detection of *Aspergillus* species at different concentrations.

Feature	Available format(s)
Catalogue Number	QAF104140_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma and/or Physiological Buffer and/or Synthetic Sputum
Panel Member Target Range	Covering Clinical Range
Panel Member Sample Volume	1.0 ml
Panel Analysis type	Qualitative, Quantative for information purposes only
Panel Sample Pre-treatment Requirement	Ready for analysis. Pre-treatment may be required for sputum. Follow test manufacturers IFU
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

CANDIDA SPP.

CANDNA25 - QAF124151

To evaluate the ability of laboratories to use molecular techniques for detection of *Candida* species.

Feature	Available format(s)
Catalogue Number	QAF124151_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma and/or Physiological Buffer
Panel Member Target Range	Covering clinical and analytical range
Sputum	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

DERMATOPHYTOSIS

DERMA25 - QAF164187

To assess laboratories ability to detect dermatophytes using their routine molecular diagnostic platform and procedures.

Feature	Available format(s)
Catalogue Number	QAF164187_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Physiological Buffer
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

PNEUMOCYSTIS JIROVECII PNEUMONIA (PCP)

PCPDNA25 - QAF114144

To assess laboratories ability in the molecular detection of *Pneumocystis jirovecii*.
To assess the sensitivity of molecular assays in routine clinical use for the detection of *P. jirovecii*.

Feature	Available format(s)
Catalogue Number	QAF114144_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Clinical material
Matrix Panel Format	Physiological Buffer
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	0.5 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis Type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

PARASITIC EQA

TRICHOMONAS VAGINALIS

TV25 - QAP184202

To assess the performance of laboratories in the detection of *Trichomonas vaginalis*.

Feature	Available format(s)
Catalogue Number	QAP184202_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport medium, Urine and/or Physiological Buffer
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	4.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

TOXOPLASMA GONDII

TGDNA25 - QAP044123

To assess the qualitative detection of *Toxoplasma gondii* at different concentrations.

Feature	Available format(s)	
Catalogue Number	QAP044123_1	QAP044123_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Amniotic Fluid and/or Plasma	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	Lyophilised	
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient	
Accreditation/Regulatory Status	Accredited to ISO17043	

MPP EQA

ARTHROPOD-BORNE VIRUSES

ARBO25 - QAM194206

The Arthropod-borne virus EQA will focus on the molecular detection and determination of different arthropod-borne viruses (including viruses from Flavi-, Toga-, Bunya-, and/or Reoviridae families). The panel is designed to represent various clinical scenarios (fever, haemorrhagic symptoms and/or neurological illness) and may include medically important arboviruses such as tick-borne encephalitis viruses, sandfly fever viruses, Japanese encephalitis viruses, Rift Valley fever viruses, Usutu virus, Murray Valley encephalitis virus, or St. Louis encephalitis virus. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

Feature	Available format(s)
Catalogue Number	QAM194206_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-Treatment Requirement	Reconstitution of lyophilised material
Panel Analysis Type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient
Accreditation/Regulatory Status	Accredited to ISO17043

BACTERIAL GASTROENTERITIS

GASTROB25 - QAB124153

Different species of pathogenic bacteria are known to cause gastroenteritis. The panel members of this EQA will resemble clinical samples and may include current clinically relevant strains of *Salmonella*, *Shigella*, *Yersinia*, *E.coli* 0157, *C. difficile* or *Campylobacter* species. The aim of the Bacterial Gastroenteritis EQA is to assess laboratories ability to detect a range of bacterial pathogens known to cause gastroenteritis using their routine molecular diagnostic platform and procedures.

Feature	Available format(s)	
Catalogue Number	QAB124153_1	QAB124153_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Synthetic Faecal Matrix and/or Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Pre-treatment may be required for SFM. Follow test manufacturers IFU	
Panel Analysis type	Qualitative.	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

CENTRAL NERVOUS SYSTEM I (VIRAL MENINGITIS AND ENCEPHALITIS)

CNSI25 - QAV174195

The central nervous system I (viral meningitis and encephalitis) EQA scheme will focus on the molecular detection and determination of various enterovirus, parechovirus, herpes simplex virus 1/2, Varicella-Zoster virus and JC virus strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

Feature	Available format(s)	
Catalogue Number	QAV174195_1	QAV174195_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured material and/or Clinical material	
Matrix Panel Format	Synthetic CSF and/or Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative. Quantitative for information purposes only	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

CENTRAL NERVOUS SYSTEM II (NON-VIRAL MENINGITIS AND ENCEPHALITIS)

CNSII25 - QAM174196

The central nervous system II (non-viral meningitis and encephalitis) EQA scheme will focus on the molecular detection and determination of various *Listeria* spp, *Neisseria meningitidis*, *Streptococcus pneumoniae*, *Streptococcus agalactiae*, *Escherichia coli* K1, *Cryptococcus* spp., *Aspergillus* spp. or *Haemophilus influenzae* strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

Feature	Available format(s)	
Catalogue Number	QAM174196_1	QAM174196_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured material and/or Clinical material	
Matrix Panel Format	Synthetic CSF and/or Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative. Quantitative for information purposes only	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

MALDI-TOF

MALDI25 - QAB124155

The primary aim of this EQA is to evaluate the ability of laboratories in the detection and determination of different clinically relevant isolates using MALDI-TOF and other similar mass spectrometry based technologies in the routine microbiology laboratory.

Feature	Available format(s)
Catalogue Number	QAB124155_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Microbiological Medium and/or Transport Medium
Panel Member Target Range	Clinically relevant range of microorganisms for detection & determination
Panel Member Sample Volume	0.5 ml
Panel Sample Pre-treatment Requirement	Culture followed by standard MALDI protocol
Panel Analysis type	Typing
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

PARASITIC GASTROENTERITIS

GASTROP25 - QAP124154

Parasites are a frequent cause of gastroenteritis and are a growing risk in this age of global travel. The panel members of this EQA will resemble clinical samples and may include current clinically relevant strains of *Giardia*, *Cryptosporidium*, *Dientamoeba*, *Blastocystis* and *Entamoeba*. The aim of the Parasitic Gastroenteritis EQA is to assess laboratories' ability to detect a range of parasitic pathogens known to cause gastroenteritis using their routine molecular diagnostic platform and procedures.

Feature	Available format(s)	
Catalogue Number	QAP124154_1	QAP124154_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured material and/or Clinical material	
Matrix Panel Format	Synthetic Faecal Matrix and/or Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Pre-treatment may be required for SFM. Follow test manufacturers IFU	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

RESPIRATORY I

RESPI25 - QAV164188

The Respiratory I EQA will focus on the molecular detection and determination of various influenza A & B and respiratory syncytial virus strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

Feature	Available format(s)	
Catalogue Number	QAB164188_1	QAV164188_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium	
Panel Member Target Range	Covering Clinical Range	
Panel Member Sample Volume	1.0ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis Type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

RESPIRATORY I PLUS

RESPIplus25 - QAM204216

The Respiratory I Plus EQA will focus on the molecular detection and determination of various influenza A & B, respiratory syncytial virus strains and SARS-Cov-2. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

Feature	Available format(s)	
Catalogue Number	QAM204216_1A	QAM204216_1B
Total Number of Challenges	1	1
Number of Panel Members	10	10
Distribution / Testing Period	Q2	Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium	
Panel Member Target Range	Covering Clinical Range	
Panel Member Sample Volume	1.0ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis Type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

RESPIRATORY II

RESPII25 - QAV164189

The Respiratory II EQA will focus on the molecular detection and determination of human metapneumovirus, respiratory adenoviruses, rhinoviruses, coronaviruses, enterovirus and parainfluenza viruses. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

Feature	Available format(s)	
Catalogue Number	QAV164189_1	QAV164189_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

RESPIRATORY III

RESPIII25 - QAM174193

The Respiratory III EQA will focus on the molecular detection and determination of various *Bordetella pertussis*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, *Streptococcus pneumoniae* or *Haemophilus influenzae* strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and to report their individual test results to QCMD.

Feature	Available format(s)	
Catalogue Number	QAM174193_1	QAM174193_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q3	Q1 & Q3
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

SEPSIS

SEPSIS25 - QAB164178

This EQA scheme consists of a range of pathogens associated with sepsis such as *Staphylococcus spp.*, *Escherichia coli*, *Enterococcus spp.*, *Streptococcus spp.*, *Klebsiella spp.*, *Pseudomonas spp.*, and *Candida spp.* The participating laboratory will be required to use their current molecular diagnostic processes and procedures for the detection and identification of microorganisms within blood or plasma based matrices.

Feature	Available format(s)
Catalogue Number	QAB164178_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Whole Blood and/or Plasma and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

SEXUALLY TRANSMITTED INFECTIONS I

STI_I25 - QAB154177

The aim of the Sexually Transmitted Infection (STI) EQA is to assess the laboratories' ability to detect a range of sexual transmitted infections known to cause disease using their routine molecular diagnostic platform and procedures. The panel members will resemble clinical samples and may include current clinically relevant strains of *Mycoplasma genitalium*, *Mycoplasma hominis*, *Trichomonas vaginalis*, *Ureaplasma urealyticum* and *Gardnerella vaginalis*.

Feature	Available format(s)	
Catalogue Number	QAB154177_1	QAB154177_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Urine and/or Physiological Buffer and/or Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	4.0ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

SEXUALLY TRANSMITTED INFECTIONS II

STI_II25 - QAM174201

The sexually transmitted infection II EQA will focus on the molecular detection and determination of various *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Treponema pallidum*, and herpes simplex virus strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and to report their individual test results to QCMD.

Feature	Available format(s)	
Catalogue Number	QAM174201_1	QAM174201_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Urine and/or Physiological Buffer and/or Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	4.0ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

TRANSPLANTATION (VIRAL)

TRANS25 - QAM174198

The viral transplant EQA scheme will focus on the molecular detection and determination of various cytomegalovirus, Epstein-Barr virus, human herpes virus 6, BK virus, B19 virus and adenovirus strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and to report their individual test results to QCMD.

Feature	Available format(s)
Catalogue Number	QAM174198_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q2
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma and/or Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative & Quantitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice
Accreditation/Regulatory Status	Accredited to ISO17043

VIRAL GASTROENTERITIS

GASTROV25 - QAV124152

Viruses are a major cause of gastroenteritis outbreaks. It has been estimated that at least 50% of foodborne gastroenteritis cases are caused by noroviruses. Approximately another 20% of cases, and the majority of severe cases in children, are due to rotavirus. Other clinically significant viral enteropathogens include adenovirus, particularly types 40 and 41, and astroviruses. The aim of the Viral Gastroenteritis EQA is to assess laboratories ability to detect a range of viral pathogens known to cause gastroenteritis using their routine molecular diagnostic platform and procedures. The panel members will resemble clinical samples and may include current clinically relevant strains of norovirus, rotavirus, astrovirus, sapovirus and adenovirus.

Feature	Available format(s)	
Catalogue Number	QAV124152_1	QAV124152_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured material and/or Clinical material	
Matrix Panel Format	Synthetic Faecal Matrix and/or Transport Medium	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Pre-treatment may be required for SFM. Follow test manufacturers IFU	
Panel Analysis type	Qualitative	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	
Accreditation/Regulatory Status	Accredited to ISO17043	

EQA PILOT STUDIES

BABESIA

BABESIA25 - QAP214219

Pathogens of the genus *Babesia* (Family: Babesiidae, Order: Piroplasmida) are important blood parasites in mammals and less frequently in birds. Of the more than 100 known tick-borne species, only a few have been identified as causing human infections. Of zoonotic importance are parasites of bovine babesiosis (*Babesia divergens* and *B. divergens*-like forms), rodent babesiosis (*B. microti*) and a few other *Babesia* species like *B. venatorum* in wild deer. During a blood meal, hard-bodied ticks (e.g. *Ixodes ricinus*) inoculate sporozoites with their saliva, which, like plasmodia, enter human erythrocytes and undergo asexual reproduction.

In Europe, *B. divergens* is the main pathogen of human babesiosis. Infections have been reported in various European countries. In the United States, *B. microti* is the agent most frequently identified. Other cases have been reported from Africa, Mexico, Japan, Taiwan and India (*B. microti* or unidentified *Babesia*).

The diagnosis of an acute infection is confirmed through identification of *Babesia* on microscopic examination or detection of *Babesia* nucleic acid. Nucleic acid testing (NAT) correlates better with active infection and more effectively identifies low-level infections than other laboratory tests, making them important for donor screening and donation testing to reduce the risk of transfusion-transmitted babesiosis.

The pilot EQA scheme will assess the proficiency of laboratories in the correct detection and identification of *Babesia* species causing human babesiosis.

Feature	Available format(s)
Catalogue Number	QAP214219_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Whole Blood
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient

BBV DRIED BLOOD SPOT



BBVDBS25 - QAM254228

Dried blood spot testing for blood borne virus diagnosis is typically used to support screening in settings where plasma or serum sampling and cold storage is challenging.

The pilot EQA scheme will assess the performance of laboratories in the detection of hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV) from dried blood spots.

Feature	Available format(s)
Catalogue Number	QAP214217_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured virus and/or Clinical material
Matrix Panel Format	Whole Blood
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	2 x 50µl
Panel Sample Pre-treatment Requirement	Extraction from dried blood spot
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	Ambient

CANDIDA AURIS



CANAUR25 - QAF254229

Candida auris (*C. auris*) is an emerging fungal pathogen associated with nosocomial infections. It is considered a serious global health threat due to its multi-drug resistance and difficulty of identification using standard methods which can misidentify *C. auris* as other phenotypically related *Candida* species. *C. auris* spreads easily in healthcare settings where some patients can develop severe and even life-threatening symptoms especially in immunocompromised patients. Early and correct identification of patients colonised with *C. auris* is critical in containing its spread.

The pilot EQA scheme will assess laboratories ability in the molecular detection and identification of *Candida auris*.

Feature	Available format(s)
Catalogue Number	QAF254229_1
Total Number of Challenges	1
Number of Panel Members	8
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Plasma and/or Physiological Buffer
Panel Member Target Range	Covering clinical and analytical range
Panel Member Sample Volume	1.0 ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice

CHAGAS

CHAGAS25 - QAP214217

Trypanosoma cruzi is the causative agent of Chagas disease or American trypanosomiasis. *T. cruzi* is primarily transmitted by triatomine bugs, known as "kissing bugs"; other transmission routes such as transplacental, blood transfusion, organ transplantation and contaminated food are known.

Since parasite detection is difficult during both the acute and the latent phase of infection, antibody detection plays a crucial role in laboratory diagnostics. Serologic testing is also the method for blood donor screening. Compared to conventional blood smears techniques, molecular tools such as PCR offer improved sensitivity for detection of acute and early congenital disease and are considered the test of choice in these settings. Also, PCR is maybe useful for monitoring reactivation in immunosuppressed patients or parasitological response to treatment.

The pilot EQA scheme will assess the proficiency of laboratories in the correct detection of *Trypanosoma cruzi* causing Chagas disease.

Feature	Available format(s)
Catalogue Number	QAP214217_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Whole Blood
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient

CYTOMEGALOVIRUS NON-BLOOD



CMVNB25 - QAV254230

Cytomegalovirus (CMV) is a betaherpes virus with a high prevalence (40-80%) in populations throughout the developed world. CMV is normally a latent lifelong infection that is completely asymptomatic in those infected with the virus.

The situation in persons with compromised immune systems such as transplant recipients is much more serious, with CMV recognised as one of the most important viral pathogens causing high rates of mortality and morbidity in these groups. It is also a highly prevalent congenital infectious agent throughout the developed world. The clinical consequences of infection may be present at birth or manifest themselves during childhood.

While blood samples are tested routinely and used for diagnosis and monitoring purposes, a range of other non-blood specimens are also extremely useful as they are non-invasive and usual have increased viral load, these samples include urine and salivary swab.

The introduction of nucleic acid amplification technologies (NAT) has led to the development of sensitive diagnostic tests that can rapidly confirm or exclude CMV infection. As a result, these tests are now of great practical and clinical relevance.

The aim of the EQA scheme is to assess the performance of molecular based assays on non-blood specimen types, which includes urine, swab and amniotic fluid.

Feature	Available format(s)	
Catalogue Number	QAV254230_1	QAV254230_2
Total Number of Challenges	1	2
Number of Panel Members	10	5
Distribution / Testing Period	Q4	Q2 & Q4
Specifications		
Sample NA Target Source	Cultured and/or Clinical material	
Matrix Panel Format	Transport Medium and/or Urine and/or Amniotic Fluid	
Panel Member Target Range	Covering clinical range	
Panel Member Sample Volume	1.0 ml	
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly	
Panel Analysis type	Qualitative.	
Panel Testing	Evaluated by various molecular methodologies	
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice	

FRANCISELLA TULARENSIS

FRATUL25 - QAB214220

Tularemia is a severe zoonotic disease and is caused by the bacteria *Francisella tularensis*. Transmission is typically through the skin or mucous membranes. For example, infection can occur when improperly cooked meat (typically rabbit) is eaten or from contaminated water is drunk, inhalation or through arthropod bites. Reservoirs of *Francisella tularensis* include lagomorphs, rodents and blood-sucking arthropods.

Laboratory confirmation of tularemia consists in detecting the bacteria in a biological sample or a specific antibody response. Molecular methods (i.e. PCR) are rapid and can allow identification of the subspecies and obviate the need for cultivation. Serological methods are routinely used for diagnosis and are considered highly specific despite cross-reactions with *Brucella*, *Yersinia*, *Proteus*, *Legionella* and *Mycoplasma* species may occur.

The pilot EQA scheme will assess the proficiency of laboratories on the detection of *Francisella tularensis*.

Feature	Available format(s)
Catalogue Number	QAB214220_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium and/or Physiological Buffer
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient

GROUP A STREPTOCOCCUS

GAS25 - QAB234226

Group A Streptococcus (GAS) is one of the most common causes of bacterial infections of the throat and skin. GAS or *Streptococcus pyogenes* is also the cause of 'Scarlet fever' which most commonly affects children between 5 and 15 years old. Early antibiotic treatment has been shown to be effective in reducing both the transmission and severity of disease therefore rapid diagnosis is key. The SARS-CoV-2 pandemic resulted in an influx of near patient / PoC molecular testing platforms, with GAS added to the test menu of several commercial instruments for use within a non-laboratory, point of impact test setting or in a 'statim' or 'out of hours' capacity within the central laboratory. We have therefore introduced a pilot EQA to assess the performance of molecular GAS testing, allowing test sites to assess the performance of their assays.

Feature	Available format(s)
Catalogue Number	QAB234226_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice

JOINT INFECTION

JOINT25 - QAM244227

Bone and Joint infection diagnosis can be challenging as the symptoms are similar to other common conditions such as gout and rheumatoid arthritis. Culturing can require up to two weeks due to the potentially fastidious nature of the pathogens associated with this type of infection. Average sensitivity rates of approximately 72% have been recorded and this can be further reduced where antibiotics have been administered.

The aim of the joint infection pilot study is to assess the ability of laboratories to detect a range of Gram positive, Gram negative and fungal pathogens alongside common resistance markers using their routine molecular diagnostic platforms and procedures. The panel members will resemble clinical samples and will include current clinically relevant strains.

Feature	Available format(s)
Catalogue Number	QAM244227_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0ml
Panel Sample Pre-treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice

MALARIA

MALARIA25 - QAP214218

Malaria is a life threatening, mosquito borne, infectious disease in humans. The causative agents of malaria are a number protozoan species of the genus *Plasmodium*.

There are five *Plasmodium* species that commonly cause disease in humans. *Plasmodium falciparum* is the causative agent for most cases of malaria (malaria tropica) and is found across Africa. *P. falciparum* and malaria tropica are the most severe form and account for the majority of malaria fatalities worldwide. *Plasmodium vivax* (malaria tertiana) is the second most prevalent species and is found mostly in Latin America and Asia, whereas *Plasmodium ovalae sensu lato*, which is also a causative agent of malaria tertiana, is mainly restricted to West African regions. *Plasmodium malariae* (malaria quartan) is found worldwide but at a relatively low incidence. *Plasmodium knowlesi* was identified as the causative agent of localised outbreaks in Malaysia and has since been reported in nearly all Southeast Asian countries.

In Europe, malaria is mainly a travel medicine issue. In patients with a fever of unknown cause and a stay in an area where malaria is endemic, acute malaria must be excluded. The diagnosis of malaria is based on microscopic, serological or molecular detection of *Plasmodium* species. Although microscopy is still the most routinely used method for diagnosis by clinical laboratories, molecular testing has become increasingly popular.

The pilot EQA scheme will assess the proficiency of laboratories in the correct detection of *Plasmodium* species.

Feature	Available format(s)
Catalogue Number	QAP214218_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Whole Blood
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	Lyophilised
Panel Sample Pre-treatment Requirement	Reconstitution of lyophilised material
Panel Analysis type	Qualitative. Quantitative for information purposes only
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	2-8°C / Lyophilised Ambient

EQA PILOT STUDIES

POXVIRUSES

POX25 - QAV224225

Due to the global outbreak of monkeypox and increasing demand for laboratory preparedness, we have introduced a pilot EQA scheme for poxviruses that will include inactivated monkeypox virus and other orthopoxviruses (Cowpox, and Vaccinia). This will offer laboratories, that have recently set up generic orthopoxvirus or specific monkeypox virus molecular diagnostics, the opportunity to assess the performance of their assays.

Feature	Available format(s)
Catalogue Number	QAV224225_1
Total Number of Challenges	1
Number of Panel Members	10
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured and/or Clinical material
Matrix Panel Format	Transport Medium
Panel Member Target Range	Covering clinical range
Panel Member Sample Volume	1.0ml
Panel Sample Pre-Treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis Type	Qualitative
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice

VIRAL METAGENOMICS NGS

NGSMETA_25 - QAV204213

Viral metagenomics has been proposed as an unbiased method with unique clinical opportunities to identify the composition of clinical specimens without introduction of selection bias due to processing methods. The techniques used in these protocols are however complex and analysis methods require standardisation. This EQA pilot study aims to assess performance of existing metagenomics protocols as currently implemented by participating laboratories. Samples will be provided which will mimic cerebrospinal fluid samples containing known viral pathogens including enterovirus, herpes simplex virus and influenza virus.

Performance will be assessed based on the qualitative identification of viruses present in the samples, at the family, genus, species and subtype levels.

Feature	Available format(s)
Catalogue Number	QAV204213_1
Total Number of Challenges	1
Number of Panel Members	5
Distribution / Testing Period	Q3
Specifications	
Sample NA Target Source	Cultured material
Matrix Panel Format	Synthetic CSF + human cell lines
Panel Member Sample Volume	1.0ml
Panel Sample Pre-Treatment Requirement	Ready for analysis. Treat as clinical samples and analyse accordingly
Panel Analysis Type	Sequence analysis
Panel Testing	Evaluated by various molecular methodologies
Storage / Shipment Conditions	<-20°C / Frozen on Dry-ice

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
Adenovirus							Page 15
ADVDNA25	QAV054133_1	1	10	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV054133_2	2	5	Q2, Q4			
Arthropod-borne viruses							Page 56
ARBO25	QAM194206_1	1	10	Q3	Ambient	Qualitative	Multi-Pathogen / Syndromic EQA
Aspergillus spp.							Page 53
ASPDNA25	QAF104140_1	1	8	Q3	Dry-ice	Qualitative	Fungal EQA
Atypical mycobacterium							Page 42
NTM25	QAB194208_1	1	10	Q1	Ambient	Qualitative	Bacterial EQA
B19 virus							Page 15
B19DNA25	QAV034116_1	1	8	Q3	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV034116_2	2	4	Q1, Q3			
Babesia							Page 64
BABESIA25	QAP214219_1	1	10	Q3	Ambient	Qualitative	Pilot Study
Bacterial 16S Ribosomal RNA							Page 42
B16SrRNA25	QAB164183_1	1	8	Q3	Dry-ice	Typing	Bacterial EQA
Bacterial Gastroenteritis							Page 56
GastroB25	QAB124153_1	1	10	Q4	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
	QAB124153_2	2	5	Q2, Q4			
BBV Dried Blood Spot							Page 65
BBVDBS25	QAM254228	1	10	Q3	Ambient	Qualitative	Pilot Study
BK virus (BKV)							Page 16
BKDNA25	QAV144166_1	1	10	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV144166_2	2	5	Q2, Q4			
Bordetella pertussis							Page 43
BPDNA25	QAB094132_1	1	10	Q2	Dry-ice	Qualitative	Bacterial EQA
Borrelia burgdorferi spp. (Lyme Disease)							Page 43
BbDNA25	QAB114147_1	1	10	Q3	Dry-ice	Qualitative	Bacterial EQA
Candida auris							Page 65
CANAUR25	QAF254229_1	1	8	Q3	Dry-ice	Qualitative	Pilot Study

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
<i>Candida spp.</i>							Page 53
CANDNA25	QAF124151_1	1	10	Q3	Dry-ice	Qualitative	Fungal EQA
Central Nervous System I (viral Meningitis and Encephalitis)							Page 57
CNSI25	QAV174195_1 QAV174195_2	1 2	10 5	Q4 Q2, Q4	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
Central Nervous System II (Non-viral Meningitis and Encephalitis)							Page 57
CNSII25	QAM174196_1 QAM174196_2	1 2	10 5	Q4 Q2, Q4	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
Chagas							Page 66
CHAGAS25	QAP214217_1	1	10	Q3	Ambient	Qualitative	Pilot Study
Chikungunya virus (CHIKV)							Page 16
CHIKV25	QAV154175_1	1	10	Q3	Ambient	Qualitative	Viral EQA
<i>Chlamydia psittaci</i>							Page 44
CPS25	QAB134165_1	1	8	Q2	Dry-ice	Qualitative	Bacterial EQA
<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>							Page 44
CTNg25	QAB174191_1 QAB174191_2	1 2	10 5	Q3 Q1, Q3	Dry-ice	Qualitative	Bacterial EQA
<i>Chlamydophila pneumoniae</i>							Page 45
CP25	QAB084107_1	1	5	Q2	Dry-ice	Qualitative	Bacterial EQA
<i>Clostridium difficile</i> (CD)							Page 45
CDDNA25	QAB084125_1 QAB084125_2	1 2	10 5	Q4 Q2, Q4	Dry-ice	Qualitative	Bacterial EQA
Coronavirus (CoV)							Page 17
CVRNA25	QAV064137_1	1	10	Q2	Dry-ice	Qualitative	Viral EQA
Cytomegalovirus (CMV) Dried Blood Spots							Page 18
CMVDBS25	QAV064127_1	1	8	Q3	Ambient	Qualitative	Viral EQA
Cytomegalovirus (CMV) Drug Resistance							Page 17
CMVDR25	QAV144169_1	1	5	Q2	Dry-ice	Drug Resistance / Sequencing	Viral EQA
Cytomegalovirus (CMV)							Page 30
CMVDNA25	QAV014120_1 QAV014120_2	1 2	10 5	Q4 Q2, Q4	Dry-ice	Qualitative & Quantitative	Viral EQA

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
Cytomegalovirus (CMV) Non-Blood							Page 67
CMVNB25	QAV254230_1	1	10	Q4	Dry-ice	Qualitative	Pilot Study
	QAV254230_2	2	5	Q2, Q4			
Cytomegalovirus (CMV) Whole Blood							Page 18
CMVWB25	QAV124150_1	1	10	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV124150_2	2	5	Q2, Q4			
Dengue virus (DENV)							Page 19
DENVRNA25	QAV114148_1	1	10	Q3	Ambient	Qualitative	Viral EQA
Dermatophytosis							Page 54
DERMA25	QAF164187_1	1	8	Q3	Dry-ice	Qualitative	Fungal EQA
Diarrheagenic <i>Escherichia coli</i>							Page 46
E.COLI25	QAB154179_1	1	8	Q3	Dry-ice	Typing	Bacterial EQA
Enterovirus (EV)							Page 19
EVRNA25	QAV984104_1	1	10	Q3	Dry-ice	Qualitative	Viral EQA
	QAV984104_2	2	5	Q1, Q3			
Enterovirus Typing (EV)							Page 20
EVT25	QAV164185_1	1	8	Q1	Dry-ice	Typing	Viral EQA
Epstein-Barr virus (EBV)							Page 20
EBVDNA25	QAV024121_1	1	10	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV024121_2	2	5	Q2, Q4			
Epstein-Barr virus (EBV) Whole Blood							Page 21
EBVWB25	QAV134161_1	1	10	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV134161_2	2	5	Q2, Q4			
Extended Spectrum β -lactamase and Carbapenemase							Page 46
ESBL25	QAB134162_1	1	8	Q3	Dry-ice	Typing	Bacterial EQA
<i>Francisella tularensis</i>							Page 68
FRATUL25	QAB214220_1	1	10	Q3	Ambient	Qualitative	Pilot Study
Group A Streptococcus							Page 69
GAS25	QAB234226_1	1	10	Q3	Dry-ice	Qualitative	Pilot Study
Group B Streptococcus							Page 47
GBS25	QAB174200_1	1	8	Q4	Dry-ice	Qualitative	Bacterial EQA

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
Helicobacter pylori							Page 47
H.PYLORI25	QAB164190_1	1	10	Q3	Dry-ice	Qualitative	Bacterial EQA
Hepatitis A virus (HAV)							Page 24
HAVRNA25	QAV124156_1	1	8	Q1	Dry-ice	Qualitative	Viral EQA
Hepatitis B virus (HBV)							Page 25
HBVDNA25	QAV994110_1	1	8	Q3	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV994110_2	2	4	Q1, Q3			
	QAV994110_4	4	4	Q1, Q2, Q3, Q4			
Hepatitis B virus (HBV) Drug Resistance							Page 21
HBVDR25	QAV124160_1	1	5	Q3	Dry-ice	Drug Resistance / Sequencing	Viral EQA
Hepatitis B virus (HBV) Genotyping							Page 22
HBVGT25	QAV064118_1	1	8	Q1	Dry-ice	Typing	Viral EQA
Hepatitis C virus (HCV)							Page 25
HCVRNA25	QAV994112_1	1	8	Q3	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV994112_2	2	4	Q1, Q3			
	QAV994112_4	4	4	Q1, Q2, Q3, Q4			
Hepatitis C virus (HCV) Drug Resistance							Page 23
HCVDR25	QAV134167_1	1	5	Q3	Dry-ice	Drug Resistance / Sequencing	Viral EQA
Hepatitis C virus (HCV) Genotyping							Page 24
HCVGT25	QAV034117_1	1	8	Q1	Dry-ice	Typing	Viral EQA
Hepatitis D virus (HDV)							Page 26
HDV25	QAV144170_1	1	8	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
Hepatitis E virus (HEV)							Page 26
HEVRNA25	QAV124157_1	1	8	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
Herpes simplex virus 1 & 2 (HSV)							Page 27
HSV DNA25	QAV994105_1	1	10	Q3	Dry-ice	Qualitative	Viral EQA
	QAV994105_2	2	5	Q1, Q3			
Herpes simplex virus Drug Resistance							Page 27
HSVDR25	QAV164184_1	1	5	Q1	Dry-ice	Drug Resistance / Sequencing	Viral EQA

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
Human herpes virus 6 (HHV6)							Page 31
HHV6DNA25	QAV084119_1	1	10	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV084119_2	2	5	Q2, Q4			
Human Immunodeficiency virus type 1 (HIV-1) – DNA							Page 28
HIVDNA25	QAV034114_1	1	8	Q3	Dry-ice	Qualitative	Viral EQA
	QAV034114_2	2	4	Q1, Q3			
Human Immunodeficiency virus type 1 (HIV-1) – Drug Resistance							Page 29
HIVDR25	QAV024131_1	1	5	Q4	Dry-ice	Drug Resistance / Sequencing	Viral EQA
Human Immunodeficiency virus type 1 (HIV-1) – Drug Resistance (Integrase)							Page 29
HIVDRint25	QAV114146_1	1	5	Q4	Dry-ice	Drug Resistance / Sequencing	Viral EQA
Human Immunodeficiency virus type 1 (HIV-1) – RNA							Page 28
HIVRNA25	QAV994108_1	1	8	Q3	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV994108_2	2	4	Q1, Q3			
	QAV994108_4	4	4	Q1, Q2, Q3, Q4			
HIV-2							Page 30
HIV2_25	QAV204212_1	1	8	Q3	Dry-ice	Qualitative	Viral EQA
Human metapneumovirus (MPV)							Page 31
MPV25	QAV054135_1	1	8	Q2	Dry-ice	Qualitative	Viral EQA
Human Papillomavirus (HPV) – PreservCyt							Page 32
HPVPRES25	QAV094130_1	1	12	Q3	Ambient / Specialist	Qualitative	Viral EQA
	QAV094130_2	2	6	Q1, Q3			
Human Papillomavirus (Surepath)							Page 33
HPVSURE25	QAV184204_1	1	12	Q3	Ambient	Qualitative	Viral EQA
Influenza A & B virus (FLU)							Page 34
INFRNA25	QAV054134_1	1	10	Q4	Dry-ice	Qualitative	Viral EQA
	QAV054134_2	2	5	Q2, Q4			
Influenza Typing							Page 34
INFTP25	QAV064138_1	1	8	Q4	Dry-ice	Typing	Viral EQA
JC virus (JCV)							Page 35
JCDNA25	QAV074106_1	1	10	Q4	Dry-ice	Qualitative & Quantitative	Viral EQA
	QAV074106_2	2	5	Q2, Q4			

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
Joint Infection							Page 70
JOINT25	QAM244227_1	1	10	Q3	Dry-ice	Qualitative	Pilot Study
Legionella spp.							Page 48
LPDNA25	QAB044122_1	1	10	Q1	Dry-ice	Qualitative	Bacterial EQA
Malaria							Page 71
MALARIA25	QAP214218_1	1	10	Q3	Ambient	Qualitative	Pilot Study
MALDI-TOF							Page 58
MALDI25	QAB124155_1	1	10	Q3	Dry-ice	Typing	Multi-Pathogen / Syndromic EQA
Measles / Mumps							Page 35
MM25	QAV144171_1	1	10	Q3	Dry-ice	Qualitative	Viral EQA
MERS coronavirus (MERS-CoV)							Page 36
MERS25	QAV154181_1	1	8	Q2	Dry-ice	Qualitative	Viral EQA
Methicillin Resistant Staphylococcus aureus (MRSA)							Page 49
MRSADNA25	QAB064124_1	1	10	Q3	Ambient	Qualitative	Bacterial EQA
Methicillin Resistant Staphylococcus aureus (MRSA) – Typing							Page 48
MRSATP25	QAB074128_1	1	8	Q3	Ambient	Typing	Bacterial EQA
Mycobacterium tuberculosis (MTB)							Page 49
MTBDNA25	QAB014129_1	1	10	Q3	Ambient	Qualitative	Bacterial EQA
	QAB014129_2	2	5	Q1, Q3			
Mycobacterium tuberculosis Drug Resistance							Page 50
MTBDR25	QAB194209_1	1	8	Q3	Ambient	Typing	Bacterial EQA
Mycoplasma genitalium							Page 50
MG25	QAB184205_1	1	10	Q3	Dry-ice	Qualitative	Bacterial EQA
Mycoplasma pneumoniae							Page 51
MP25	QAB174192_1	1	5	Q2	Dry-ice	Qualitative	Bacterial EQA

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
Norovirus (NV)							Page 36
NVRNA25	QAV084139_1	1	10	Q4	Dry-ice	Qualitative	Viral EQA
	QAV084139_2	2	5	Q2, Q4			
Parainfluenza virus (PIV)							Page 37
PINFRNA25	QAV064136_1	1	10	Q2	Dry-ice	Qualitative	Viral EQA
Parasitic Gastroenteritis							Page 58
GastroP25	QAP124154_1	1	10	Q4	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
	QAP124154_2	2	5	Q2, Q4			
Parechovirus (HPeV)							Page 37
PeVRNA25	QAV114145_1	1	10	Q3	Dry-ice	Qualitative	Viral EQA
	QAV114145_2	2	5	Q1, Q3			
Pneumocystis jirovecii pneumonia (PCP)							Page 54
PCPDNA25	QAF114144_1	1	10	Q3	Dry-ice	Qualitative	Fungal EQA
Poxviruses							Page 72
POX25	QAV224225_1	1	10	Q3	Dry-ice	Qualitative	Pilot Study
Respiratory I							Page 59
RESPI25	QAV164188_1	1	10	Q3	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
	QAV164188_2	2	5	Q1, Q3			
Respiratory I Plus							Page 59
RESPIplus25	QAM204216_1A	1	10	Q2	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
	QAM204216_1B	1	10	Q4			
Respiratory II							Page 60
RESPII25	QAV164189_1	1	10	Q3	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
	QAV164189_2	2	5	Q1, Q3			
Respiratory III							Page 60
RESPIII25	QAM174193_1	1	10	Q3	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
	QAM174193_2	2	5	Q1, Q3			
Respiratory syncytial virus (RSV)							Page 38
RSV25	QAV054142_1	1	10	Q4	Dry-ice	Qualitative	Viral EQA
	QAV054142_2	2	5	Q2, Q4			

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
Rhinovirus (RV)							Page 38
RVRNA25	QAV064143_1	1	10	Q2	Dry-ice	Qualitative	Viral EQA
SARS-CoV-2							Page 39
SCV2_25	QAV204215_1A	1	5	Q1	Dry-ice	Qualitative	Viral EQA
	QAV204215_1B	1	5	Q2			
	QAV204215_1C	1	5	Q3			
	QAV204215_1D	1	5	Q4			
Sepsis							Page 61
SEPSIS25	QAB164178_1	1	10	Q3	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
Sexually Transmitted Infections I							Page 61
STI_I25	QAB154177_1	1	10	Q4	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
	QAB154177_2	2	5	Q2, Q4			
Sexually Transmitted Infections II							Page 62
STI_II25	QAM174201_1	1	10	Q4	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
	QAM174201_2	2	5	Q2, Q4			
Syphilis							Page 51
SYPH25	QAB154180_1	1	8	Q3	Dry-ice	Qualitative	Bacterial EQA
Torque teno virus (TTV)							Page 39
TTV25	QAV184203_1	1	6	Q4	Dry-ice	Qualitative	Viral EQA
Toxoplasma gondii							Page 55
TGDNA25	QAP044123_1	1	10	Q3	Ambient	Qualitative	Parasitic EQA
	QAP044123_2	2	5	Q1, Q3			
Transplantation (viral)							Page 62
TRANS25	QAM174198_1	1	10	Q2	Dry-ice	Qualitative & Quantitative	Multi-Pathogen / Syndromic EQA
Trichomonas vaginalis							Page 55
TV25	QAP184202_1	1	8	Q3	Dry-ice	Qualitative	Parasitic EQA
Vancomycin Resistant Enterococci (VRE)							Page 52
VRE25	QAB134163_1	1	10	Q3	Dry-ice	Typing	Bacterial EQA

APPENDIX I: SUMMARY SPECIFICATIONS AND DISTRIBUTION SCHEDULE

TARGET PATHOGEN							PAGE NUMBER
SCHEME CODE	CATALOGUE NUMBER	NO. OF CHALLENGES	PANEL MEMBERS PER CHALLENGE	DISTRIBUTION DATE(S)/ TESTING PERIOD	SHIPPING CONDITIONS	ANALYSIS TYPE	SCHEME TYPE
Varicella-Zoster virus (VZV)							Page 40
VZVDNA25	QAV034103_1 QAV034103_2	1 2	10 5	Q3 Q1, Q3	Dry-ice	Qualitative	Viral EQA
Viral Gastroenteritis							Page 63
GastroV25	QAV124152_1 QAV124152_2	1 2	10 5	Q4 Q2, Q4	Dry-ice	Qualitative	Multi-Pathogen / Syndromic EQA
Viral Metagenomics NGS							Page 72
NGSmeta_25	QAV204213_1	1	5	Q3	Dry-ice	Sequencing	Pilot Study
West Nile virus (WNV)							Page 40
WNV RNA25	QAV104141_1	1	10	Q3	Ambient	Qualitative	Viral EQA
Yellow Fever Virus							Page 41
YFV25	QAV194207_1	1	8	Q3	Ambient	Qualitative	Viral EQA
Zika Virus							Page 41
ZIKA25	QAV164186_1	1	10	Q3	Ambient	Qualitative	Viral EQA



www.qcmd.org