



CLS

Clinical Microbiology Laboratory Scheme

Scheme Description

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CLS Scheme Description

Record of issue status and modifications

ISSUE	ISSUE DATE	DETAILS	AUTHORISED BY
1	Oct 2018	Version 1 issued.	K. Morgan
2	Mar 2019	Added UKAS logo	A.McCarthy
3	Sept 2019	Removed 'Standards' from page one. Added new PNE and CRG samples. Added extra information regarding AFB sample.	A.McCarthy K. Morgan

Notes:

Where this document has been translated, the English version shall remain the definitive version

Scheme Aims and Organisation

The primary aim of the Clinical Microbiology Laboratory proficiency testing scheme (CLS) is to enable laboratories performing the microbiological analysis of clinical samples to monitor their performance and compare it with that of their peers. The CLS scheme also aims to provide information to participants on technical issues and methodologies relating to Clinical Microbiology.

The CLS scheme year operates from January to December. Further information about CLS, including test material availability, round despatch dates and reporting deadlines, are available on the current CLS application form.

The operation of the scheme is supported by an Advisory Group consisting of experts in the field of Clinical Microbiology. The scheme is run in collaboration with the American Proficiency Institute (API). The scheme reports on the performance of U.K. participants to the National Quality Assurance Advisory Panel for Medical Microbiology.

Test Materials

Details of test materials available in CLS are given in Appendix A. The test parameters are continually reviewed to ensure they meet the needs of current laboratory testing and regulatory requirements.

Note: All test materials provided are intended for use as proficiency testing materials only and are not to be used for any other purposes.

Some aspects of the scheme, such as test material production, homogeneity testing and stability assessment, can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and LGC is responsible for this work. The planning of the scheme, the evaluation of performance and the authorisation of the final report will never be subcontracted.

Statistical Analysis

Information on the statistics used in CLS can be found in the General Protocol and in the Scheme Report. Methods for determining assigned values and the values for SDPA used for individual samples are given in Appendix A.

Methods

Methods are listed in PORTAL. Please select the most appropriate method from the list. If none of the methods are appropriate, then please report your method as 'Other' and record a brief description in the Comments Section in PORTAL.

Results and Reports

CLS results are returned through our electronic reporting software, PORTAL, full instructions for which are provided by email. However, participants may request result submission forms on which to report and return results if they are unable to report through electronic means. This will incur an additional charge.

CLS reports will be available on the website within 10 working days of round closure. Participants will be emailed a link to the report when it is available.

APPENDIX A - Description of abbreviations used

Assigned Value (AV)

The assigned value may be derived in the following ways:

- From the robust mean (RMean). This is the median of participant results after the removal of test results that are inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors. Generally, the assigned value will be set using results from all methods, unless the measurement is considered method-dependant, in which case the assigned value will be set by method as illustrated in the report tables.

For some analytes, where there is a recognised reference method for that type of measurement, this may be used as the assigned value for a particular analyte i.e. it would be applied to results obtained by any method.

Traceability: Assigned values which are derived from the participant results, or a subset of the results are not traceable to an international measurement standard. The uncertainty of assigned values derived in this way is estimated from the participant results, according to ISO 13528.

- From a formulation value (Formulation). This denotes the use of an assigned value derived from sample preparation details, where known and exact quantities of analyte have been used to prepare the sample.

Traceability: Assigned values calculated from the formulation of the test sample are traceable, via an unbroken metrological traceability chain, to an international measurement standard. The measurement uncertainty of the assigned value is calculated using the contributions from each calibration in the traceability chain.

- From a qualitative formulation (Qual Form). This applies to qualitative tests where the assigned value is simply based on the presence/absence of the analyte in the test material.

Traceability: Assigned values calculated from the qualitative formulation of the test sample are traceable to a certified reference standard or a microbiological reference strain.

- From expert labs (Expert). The assigned value for the analyte is provided by an 'expert' laboratory.

Traceability: Assigned values provided by an 'expert' laboratory may be traceable to an international measurement standard, according to the laboratory and the method used. The uncertainty of measurement for an assigned value produced in this way will be provided by the laboratory undertaking the analysis. Details of traceability and the associated uncertainty will be provided in the report for the scheme/round.

Range

This indicates the concentration range at which the analyte may be present in the test material.

SDPA

SDPA represents the 'standard deviation for proficiency assessment' which is used to assess participant performance for the measurement of each analyte. Wherever possible, the SDPA is based on a concentration dependent model derived from historic data. Otherwise the SDPA is based upon the RobustSD.

Units

This indicates the units used for the assessment of data. These are the units in which participants should report their results. For some analytes in some schemes participants may have a choice of which units to report their results, however, the units stipulated in this scheme description are the default units to which any results reported using allowable alternative results will be converted to.

DP

This indicates the number of decimal places to which participants should report their measurement results.

CDM

Concentration Dependent Model

Bacteriology

Sample BTP

Participants will receive:

***Bordetella pertussis/parapertussis* - molecular**

2 x 1.0ml liquid samples (A and B). Simulated respiratory samples containing chemically modified, non-infectious bacterial cells.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Bordetella pertussis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Bordetella parapertussis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

Sample CDF

Participants will receive:

***C. difficile* Toxin/Antigen**

3 x 1.0ml liquid samples (A, B, and C). Simulated faecal samples containing heat inactivated *C. difficile*.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>C. difficile</i> Toxin	Antigen or Molecular	Pos/Neg	Qual Form	NA	NA	NA
<i>C. difficile</i> Antigen	Antigen	Pos/Neg	Qual Form	NA	NA	NA

Sample CGC

Participants will receive:

***C. trachomatis* and *N. gonorrhoeae* – molecular**

5 x 1.0ml liquid samples (A, B, C, D, and E). Simulated genital/urinary samples in specimen transport media containing non-infectious bacterial cells.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Chlamydia trachomatis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Neisseria gonorrhoeae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

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Sample COM

Participants will receive:

Comprehensive Bacteriology

4 x lyophilized swabs and/or lyophilized pellet in vials with diluent . Simulated patient cultures from various sources containing lyophilized bacteria on swabs and/or a lyophilized pellet with diluent.

Analyte	Method	Range	AV	SDPA	Units	DP
Blood culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA
Blood culture susceptibility	Antimicrobial susceptibility testing	Qualitative	Qual Form	NA	NA	0
CSF culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA
CSF culture susceptibility	Antimicrobial susceptibility testing	Qualitative	Qual Form	NA	NA	0
Ear/Eye culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA
Group B Strep culture	Culture isolation and identification	Qualitative	Qual Form	NA	NA	NA
<i>N. gonorrhoeae</i> culture	Culture isolation and identification	Qualitative	Qual Form	NA	NA	NA
Sputum culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA
Sputum culture susceptibility	Antimicrobial susceptibility testing	Qualitative	Qual Form	NA	NA	0
Stool culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA
Throat culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA
Urine colony count	Quantitative culture	Qualitative	Qual Form	NA	CFU/mL	NA
Urine culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA
Urine culture susceptibility	Antimicrobial susceptibility testing	Qualitative	Qual Form	NA	NA	0
Wound culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA
Wound culture susceptibility	Antimicrobial susceptibility testing	Qualitative	Qual Form	NA	NA	0

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Sample VGS

Participants will receive:

Gram Stain – Direct Smear

2 x virtual Gram stained slides (A and B). Virtual images of Gram stained smears from various patient sources.

Analyte	Method	Range	AV	SDPA	Units	DP
Gram Stain Interpretation	Microscopic interpretation and/or quantification	Multi-qualitative	Qual Form	NA	NA	NA
Leukocytes	Microscopic quantitation	Qualitative	Qual Form	NA	NA	NA
Stain Quality	Microscopic interpretation	Qualitative	Qual Form	NA	NA	NA
Sputum Specimen Quality	Microscopic interpretation	Qualitative	Qual Form	NA	NA	NA

Sample GSV

Participants will receive:

Gram Stain – Vaginitis

2 x virtual Gram stain slides (A and B). Virtual images of Gram stained patient vaginal smears.

Analyte	Method	Range	AV	SDPA	Units	DP
Bacterial vaginosis	Microscopic interpretation	Qualitative	Qual Form	NA	NA	NA
Nugent Score	Quantitative scoring	Multi-qualitative	Qual Form	NA	NA	NA

Sample GBS

Participants will receive:

Group B Strep - molecular

5 x lyophilized swabs (A, B, C, D, and E). Simulated genital samples containing lyophilized bacteria on a swab.

Analyte	Method	Range	AV	SDPA	Units	DP
Group B Strep	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

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Sample LG

***Legionella pneumophila* Antigen**

Participants will receive:

2 x 0.5ml liquid samples (A and B). Simulated urine samples containing heat inactivated *Legionella pneumophila*.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Legionella pneumophila</i> Antigen	Antigen	Pos/Neg	Qual Form	NA	NA	NA

Sample MRS

Methicillin-Resistant *Staphylococcus aureus* culture

Participants will receive:

2 x lyophilized swabs (A and B). Simulated patient samples containing lyophilized bacteria on a swab.

Analyte	Method	Range	AV	SDPA	Units	DP
Methicillin-Resistant <i>Staphylococcus aureus</i> culture	Culture isolation and identification	Pos/Neg	Qual Form	NA	NA	NA

Sample MRM

Methicillin-Resistant/Methicillin-Sensitive *Staphylococcus aureus* - molecular

Participants will receive:

2 x lyophilized swabs (A and B). Simulated patient samples containing lyophilized bacteria on a swab.

Analyte	Method	Range	AV	SDPA	Units	DP
Methicillin-Resistant <i>Staphylococcus aureus</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Staphylococcus aureus</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

Sample MPM

***Mycoplasma pneumoniae* – molecular**

Participants will receive:

2 x 1ml liquid samples (A and B). Simulated nasopharyngeal washings with chemically modified, non-infectious bacterial cells.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Mycoplasma pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

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Sample SPN

Participants will receive:

***Streptococcus pneumoniae* Antigen**

2 x 0.5ml liquid samples (A and B). Simulated urine samples containing heat inactivated *Streptococcus pneumoniae*.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Streptococcus pneumoniae</i> Antigen	Antigen	Pos/Neg	Qual Form	NA	NA	NA

Sample SPY

Participants will receive:

***Streptococcus pharyngeal* - molecular**

5 x lyophilized swabs (A, B, C, D, and E). Simulated patient throat swabs containing lyophilized bacteria.

Analyte	Method	Range	AV	SDPA	Units	DP
Group A Strep	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Group C/G Strep	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

Sample VRM

Participants will receive:

Vancomycin-Resistant Enterococcus - molecular

2 x lyophilized swabs (A and B). Simulated patient samples containing lyophilized bacteria on a swab.

Analyte	Method	Range	AV	SDPA	Units	DP
Vancomycin-Resistant Enterococcus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

Sample VRE

Participants will receive:

Vancomycin-Resistant Enterococcus Culture

2 x lyophilized swabs (A and B). Simulated patient samples containing lyophilized bacteria on a swab.

Analyte	Method	Range	AV	SDPA	Units	DP
Vancomycin-Resistant Enterococcus	Culture isolation and identification	Pos/Neg	Qual Form	NA	NA	NA

Mycobacteriology

Sample AFB

Participants will receive:

Acid Fast Smears

3 x single-well glass slides (A, B, and C). Formalin fixed bacterial and/or mycobacterial organisms dried on a glass slide representing a concentrated clinical specimen.

Analyte	Method	Range	AV		SDPA	Units	DP
Acid Fast Bacilli Smear	Microscopic interpretation	Pos/Neg	Qual Form		NA	NA	NA

Sample MTM

Participants will receive:

***Mycobacterium tuberculosis* – molecular**

2 x 1ml liquid samples (A and B). Simulated sputum samples with chemically modified, non-infectious bacterial cells.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Mycobacterium tuberculosis</i> complex	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Rifampin resistance	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

Sample MTB

Participants will receive:

Mycobacteriology Culture

3 x lyophilized loops and/or liquid samples (A, B, and C). Simulated patient samples from various sources containing mycobacteria in liquid samples and/or lyophilized on loops.

Analyte	Method	Range	AV	SDPA	Units	DP
Mycobacteriology culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA

Mycology

Sample MY

Participants will receive:

Mycology Culture

5 x lyophilized swabs (A, B, C, D, and E). Simulated patient cultures containing fungus, yeast and aerobic actinomycetes lyophilized on swab.

Analyte	Method	Range	AV	SDPA	Units	DP
Mycology culture ID	Culture isolation and identification	Multi-qualitative	Qual Form	NA	NA	NA

Parasitology

Sample BPS

Participants will receive:

Blood Parasites

3 x Giemsa stained blood smears (A, B, and C);
2 x virtual Giemsa stained blood smears (D and E). Giemsa stained thick and/or thin patient blood smears containing various blood parasites.

Analyte	Method	Range	AV	SDPA	Units	DP
Blood parasite ID	Microscopic identification	Multi-qualitative	Qual Form	NA	NA	NA

Sample TCH

Participants will receive:

Trichomonas vaginalis

3 x 2ml liquid samples (A, B, and C). Simulated genital samples in transport media with stabilised microorganisms.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Trichomonas vaginalis</i>	Antigen or Molecular	Pos/Neg	Qual Form	NA	NA	NA

Sample CRG

Participants will receive:

***Giardia & Cryptosporidium* Antigens**

3 x 1ml liquid samples (A, B, and C). Simulated faecal samples in formalin with stabilised microorganisms.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Cryptosporidium</i> Antigen	Antigen	Pos/Neg	Qual Form	NA	NA	NA
<i>Giardia</i> Antigen	Antigen	Pos/Neg	Qual Form	NA	NA	NA

Virology

Sample HPV

Participants will receive:

Human papillomavirus – molecular

5 x 1ml preservative solution with cells containing HPV (A, B, C, D, and E). Simulated cervical samples with chemically modified, non-infectious virus cells.

Analyte	Method	Range	AV	SDPA	Units	DP
HPV	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
HPV genotyping	Molecular	Multi-qualitative	Qual Form	NA	NA	NA

Sample VIR

Participants will receive:

Respiratory Virology

4 x 1ml liquid samples (A, B, C and D). Simulated nasopharyngeal samples containing inactivated virus in storage buffer.

Analyte	Method	Range	AV	SDPA	Units	DP
RSV Antigen	Antigen or Molecular	Pos/Neg	Qual Form	NA	NA	NA
Influenza A Antigen	Antigen or Molecular	Pos/Neg	Qual Form	NA	NA	NA
Influenza B Antigen	Antigen or Molecular	Pos/Neg	Qual Form	NA	NA	NA
Influenza A or B Antigen	Antigen or Molecular	Pos/Neg	Qual Form	NA	NA	NA
Adenovirus Antigen	Antigen or Molecular	Pos/Neg	Qual Form	NA	NA	NA

Sample ROT

Participants will receive:

Rotavirus Antigen

3 x 1ml liquid samples (A, B, and C). Simulated faecal samples containing inactivated rotavirus in storage buffer.

Analyte	Method	Range	AV	SDPA	Units	DP
Rotavirus Antigen	Antigen or Molecular	Pos/Neg	Qual Form	NA	NA	NA

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Molecular Multiplex

Sample BCP

Participants will receive:

Blood Pathogen Panel (multiplex)

5 x 1ml liquid samples (A, B, C, D, and E). Simulated blood cultures with chemically modified, non-infectious bacterial and fungal cells.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Acinetobacter</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Acinetobacter baumannii</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Citrobacter</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Enterobacteriaceae	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Enterobacter</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Enterobacter cloacae</i> complex	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Enterococcus</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Enterococcus faecalis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Enterococcus faecium</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Escherichia coli</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Haemophilus influenzae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Klebsiella oxytoca</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Klebsiella pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Listeria</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Listeria monocytogenes</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Neisseria meningitidis</i>	Molecular	Detected /	Qual Form	NA	NA	NA

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Analyte	Method	Range	AV	SDPA	Units	DP
		Not Detected				
<i>Proteus</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Pseudomonas aeruginosa</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Serratia marcescens</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Staphylococcus</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Staphylococcus aureus</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Staphylococcus epidermidis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Staphylococcus lugdunensis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus agalactiae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus anginosus</i> group	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus pyogenes</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Candida albicans</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Candida glabrata</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Candida krusei</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Candida parapsilosis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Candida tropicalis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: <i>mecA</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

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Analyte	Method	Range	AV	SDPA	Units	DP
Resistance Gene: vanA/B	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: vanA	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: vanB	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: KPC	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: CTX-M	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: IMP	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: NDM	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: OXA	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: VIM	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

Sample GIP

Participants will receive:

Gastrointestinal Panel (multiplex)

5 x 1ml liquid samples (A, B, C, D, and E). Simulated faecal samples with chemically modified, non-infectious bacterial and parasitic cells and intact viral particles.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Campylobacter</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>C. difficile</i> toxin A/B	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Enteroaggregative <i>E. coli</i> (EAEC)	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Enteropathogenic <i>E. coli</i> (EPEC)	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Enterotoxigenic <i>E. coli</i> (ETEC)lt/st	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>E. coli</i> O157	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Plesiomonas shigelloides</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

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Analyte	Method	Range	AV	SDPA	Units	DP
<i>Salmonella</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Shigella</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Shiga-like toxin producing <i>E. coli</i> (STEC) stx1/stx2	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Shigella</i> / Enteroinvasive <i>E. coli</i> (EIEC)	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Shiga Toxin 1	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Shiga Toxin 2	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Vibrio</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Vibrio cholerae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Yersinia enterocolitica</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Cryptosporidium</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Cyclospora cayetanensis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Entamoeba histolytica</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Giardia lamblia</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Adenovirus F 40/41	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Astrovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Norovirus GI/GII	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Rotavirus A	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Sapovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

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Sample MEP

Participants will receive:

Meningitis Panel (multiplex)

5 x 1ml liquid samples (A, B, C, D, and E). Simulated CSF with chemically modified, non-infectious bacterial and fungal cells and intact viral particles.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Escherichia coli</i> K1	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Haemophilus influenzae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Listeria monocytogenes</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Neisseria meningitidis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus agalactiae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Cytomegalovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Enterovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Herpes simplex virus 1	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Herpes simplex virus 2	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Human herpes virus 6	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Human parechovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Varicella zoster virus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Cryptococcus neoformans/gatti</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

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Sample PNE*

Participants will receive:

Pneumonia Panel (multiplex)

5 x 0.5ml liquid samples (A, B, C, D, and E). Simulated Sputum/BAL with chemically modified, non-infectious bacterial and fungal cells and intact viral particles.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Acinetobacter</i> (ACB) complex	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Chlamydia pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Enterobacter cloacae</i> complex	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Escherichia coli</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Haemophilus influenzae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Klebsiella aerogenes</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Klebsiella oxytoca</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Klebsiella pneumoniae</i> group	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Legionella pneumophila</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Moraxella catarrhalis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Mycoplasma pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Proteus</i> sp.	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Pseudomonas aeruginosa</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Serratia marcescens</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Staphylococcus aureus</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

CLS Scheme Description

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Streptococcus agalactiae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Streptococcus pyogenes</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Adenovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Coronavirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Human Metapneumovirus (hMPV)	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Human Rhinovirus / Enterovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Influenza A	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Influenza B	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Parainfluenza virus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Respiratory Syncytial Virus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: CTX-M	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: IMP	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: KPC	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: mecA/C & MREJ	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: NDM	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: OXA-48	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Resistance Gene: VIM	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

*Test material currently not included in LGC's UKAS Scope of Accreditation

CLS Scheme Description

Sample RSP

Participants will receive:

Respiratory Panel (multiplex)

5 x 1ml liquid samples (A, B, C, D, and E). Simulated nasopharyngeal washings with chemically modified, non-infectious bacterial cells and intact viral particles.

Analyte	Method	Range	AV	SDPA	Units	DP
<i>Bordetella holmesii</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Bordetella pertussis</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>B. parapertussis/ bronchiseptica</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Chlamydophila pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
<i>Mycoplasma pneumoniae</i>	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Adenovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Coronavirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Coronavirus 229E	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Coronavirus HKU1	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Coronavirus NL63	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Coronavirus OC43	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Human Metapneumovirus (hMPV)	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Human Rhinovirus / Enterovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Influenza A	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Influenza A H1	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA

CLS Scheme Description

Analyte	Method	Range	AV	SDPA	Units	DP
Influenza A H3	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Influenza A / H1-2009	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Influenza B	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Parainfluenza 1	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Parainfluenza 2	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Parainfluenza 3	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Parainfluenza 4	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Respiratory Syncytial Virus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
RSV A	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
RSV B	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA
Rhinovirus	Molecular	Detected / Not Detected	Qual Form	NA	NA	NA