Healthcare
Advanced guide

Normec
Latis Scientific

Ensuring the best quality
and safety, everywhere

Contents

Healthcare Advanced:

Providing quality through accreditation ISO 17025

We have more than 30 years' experience in the provision of laboratory analysis, surveillance projects and technical services for the healthcare industry. Our services meet relevant standards, including: HTM01-06, HTM01-01 and Renal Association guidelines.

Our UKAS accredited laboratory offers a high quality, tailored service, called Healthcare Advanced, for sterile service departments, medical device manufacturers and service contractors, providing analysis for:

- Instrument washer-disinfectors
- Endoscope washer-disinfectors
- Reverse Osmosis (RO) water supplies
- Endoscope storage and drying cabinets
- Renal dialysis
- Steam sterilisers
- Heater-cooler units
- Potable water systems.

As a Healthcare Advanced customer, you'll be provided with bespoke validation kits for endoscope reprocessors, and your account will be handled by a dedicated healthcare client liaison officer. They'll report all your results and handle your logistical needs, ensuring your on-site engineers are communicated with for the safe delivery and collection of all testing kits.

Why choose Healthcare Advanced?

- Account handled by a dedicated healthcare client liaison officer who will report all your results and handle your logistical needs.
- Choice and flexibility in testing methodology including rapid microbiological methods and molecular capabilities, providing accurate, reliable data to help inform decisions.
- Bespoke validation kits for endoscope reprocessors will be available at the right time and in the right place using our fleet of refrigerated, GPS tracked vans, providing a fully auditable chain of custody.
- UKAS accredited 5-day shelf life of disinfection efficacy surrogates allowing kits to be delivered to site in advance of an engineer's visit.
- Expert analytical data interpretation and customised results certificates providing you with the information you need quickly and accurately.

For all enquiries call 020 8853 3900 or visit our website **norm.ec/latisscientific**

Washer-disinfectors

Different types of washer-disinfectors may be found in healthcare facilities which are used to clean and disinfect equipment such as bedpans, surgical instruments, dental instruments and flexible endoscopes.

Periodic validation tests for surgical instrument washers and flexible endoscope washers are outlined in the HTM 01-01 and HTM 01-06 series of documents.

Surgical instrument washer-disinfectors

Normec Latis Scientific determinand code	Determinand	Reporting limit	Units	UKAS accreditation for purified waters	Satisfactory results for rinse water (HTM 01-01 part D)
HMETAL01	Heavy metals	0.1	mg/l	No	≤10
Appear01	Appearance	n/a	n/a	No	Clear, colourless
pH05	pH	2 - 13	pH unit	Yes	5.5 – 8.0
EC02	Electrical conductivity @ 25°C	5	µs/cm	No	≤30
Hard01	Hardness, total as $CaCO_3$	10	mg/l	Yes	≤50
Chloride07	Chloride	0.5	mg/l	No	≤10
Fe04	Iron, total	0.05	mg/l	Yes	≤2
Silicate01	Silicate, soluble	0.1	mg/l	No	≤0.2
P11	Phosphorus, total as P_2O_5	0.046	mg/l	Yes	≤0.2
Solids24	Total dissolved solids – meter from electrical conductivity 25°C	5	mg/l	No	≤40

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	Satisfactory results for rinse water (HTM 01-01 part D)
TVC_17	Total viable count @ 35°C (average from duplicate)	0 - 100	cfu/ 100 ml	Yes	≤100
ENDOTOX	Bacterial endotoxin	0.01 - 1.0	EU/ml	Yes	≤0.25

Flexible endoscope washer-disinfectors

We offer a complete set of water testing for weekly, quarterly, and yearly validations, as well as cleaning efficacy test soils and surrogate devices as required.

Our endoscope validation kits include all the elements below as standard but can also be tailored to your individual needs.

All of the components for validation have been rigorously tested to ensure they work together accurately, and a full range of logistics solutions ensure kits are returned to the laboratory within all UKAS set parameters to give truly representative results. Kits provided in line with HTM 01-06, ISO 15883, WHTM 01-06.

Validation kits for endoscope reprocessors (AERs – Automated Endoscope Reprocessors)

All water sample bottles are pre-registered on our system, saving you time on site and facilitating trend analysis of your results. Quarterly and annual kits are delivered in cool boxes with consumables required.

Temperature controlled drop off points & refrigerated vehicles ensure the stability of the samples submitted.

- Disinfection efficacy surrogates
- Self-disinfection surrogates
- Test soils
- Pre-labelled bottles
- Consumables (aprons, gloves, syringes, ice packs, etc)

Weekly water testing

Oxidase testing is carried out where the weekly bacterial count is greater than 10cfu/100 ml to presumptively identify Pseudomonas species. If positive, we will investigate further to determine the presence of *Pseudomonas aeruginosa* (as advised in HTM 01-06 Part E Testing Methods Table 2 Notes).

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	Satisfactory results (HTM 01-06)
TVC_28	Total viable count @ 30°C	0 - 100	cfu/ 100 ml	Yes	≤10

Normec Latis Scientific determinand code	Determinand	Reporting limits	Units	UKAS accreditation for purified waters	Satisfactory results (HTM 01-06)
EC02	Electrical conductivity @ 25°C	5	µs/cm	No	≤40
Hard01	Hardness, total as $CaCO_3$	10	mg/l	Yes	≤50

Quarterly water testing

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	Satisfactory results (HTM 01-06)
Appear01	Appearance	n/a	n/a	No	Clear, colourless
EC02	Electrical conductivity @ 25°C	5	µs/cm	No	≤40
Hard01	Hardness, total as $CaCO_3$	10	mg/l	Yes	≤50
pH05	pH	2 - 13	pH Unit	Yes	5.5 – 8.0
TOC-man3LL	Total organic carbon	0.1	mg/l	No	≤1

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	Satisfactory results (HTM 01-06)
TVC_28	Total viable count @ 30°C	0 - 100	cfu/100 ml	Yes	≤10
P_AERU1	*Pseudomonas aeruginosa*	0 - 100	cfu/100 ml	Yes	Not detected
ENV_MYC014	Environmental mycobacteria	0 - 100	cfu/100 ml	Yes	Not detected

Cleaning efficacy test soils

Test soils are produced according to ISO 15883-5 Annex R and are used to qualitatively assess cleaning efficacy onsite. Surrogate devices, brush and syringes are available on request.

Disinfection efficacy surrogate devices

Surrogate devices for the testing of chemical disinfection efficacy are available for a variety of specifications to meet clients' requirements.

Endoscope storage cabinets

Endoscope storage cabinets provide a controlled environment where decontaminated endoscopes can be stored safely without being re-contaminated. Thorough drying following reprocessing is therefore crucial to prevent bacterial growth and potential transmission of infections to patients. Regular monitoring is required to test the cabinet environment for fungal, bacterial count & total viable count.

Sample kits for drying & storage cabinets are delivered to healthcare advanced customers with all necessary consumables incl. TSA Settle & Contact plates and bespoke storage and drying cabinets (DC) surrogates.

Surface contact plates

The efficacy of the cleaning and disinfection of the internal surfaces of the storage cabinet chambers is verified by determining the contamination levels inside the chamber using contact plates.

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation
DryCCBac_1	Bacterial count @ 30°C/5 days	0 - 100	cfu/plate	Yes
DryCCFun_1	Fungal count @ 30°C/5 days	0 - 100	cfu/plate	Yes
DryCCTVC_1	Total viable count @ 30°C/5 days (plate)	0 - 100	cfu/plate	Yes

Air plates

Sterile surrogates are made to client specifications and installed in the cabinets. They are removed after the maximum storage period and Airborne microbial contamination is evaluated using either active sampling air plates or sedimentation plates.

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation
DryCCBac_1	Bacterial count @ 30°C/5 days	0 - 100	cfu/plate	Yes
DryCCFun_1	Fungal count @ 30°C/5 days	0 - 100	cfu/plate	Yes
DryCCTVC_1	Total viable count @ 30°C/5 days (plate)	0 - 100	cfu/plate	Yes

Sterile surrogate endoscope devices

Sterile surrogates are made to client specifications and installed in the cabinets. They are removed after the maximum storage period and tested to check that the cabinet is capable of maintaining the microbiological integrity of the endoscopes intended to be stored inside.

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation
DryCFun_2	Fungal count @ 30°C/5 days (endoscope)	0 - 100	cfu/endoscope surrogate	No
DryCTotal	Total viable count @ 30°C/5 days (endoscope)	0 - 100	cfu/endoscope surrogate	No
DryCTVC_2	Bacterial count @ 30°C/5 days (endoscope)	0 - 100	cfu/endoscope surrogate	No

Renal dialysis

Dialysis treatments can mean that patients are exposed to a large volume of water. Ensuring the quality of dialysis water is therefore essential. Normec Latis Scientific offers dialysis water quality testing according to the clinical practice guidelines by the UK Renal Association and Association of Renal Technologists and BS EN ISO 23500-3 (2024).

Our renal dialysis service provides all the relevant microbiological and chemical testing requirements to ensure that the ultrapure water required for dialysis, including haemodiafiltration, is of the appropriate standard.

- Weekly, monthly & quarterly suites in line with clinical practice guidelines offered
- Microbiological and chemical analysis for dialysis water quality (RATM/RA suites)
- Microbiological testing at the required sensitivity depending on the type of dialysis
- UKAS accredited result and low-level limit of detection for endotoxins <0.01 EU/ml
- Rapid turnaround options available for endotoxins & chemical testing

Our in-house methodology MIC048 - Determination of Total Viable Counts at 22°C (Heterotrophic Plate Count) by Filtration - Waters for Haemodialysis, follows the recently published guidelines of the ISO 23500 part 3 (2024).

Normec Latis Scientific suite	Normec Latis Scientific determinand code	Determinand	Reporting limit (chemistry) reporting range (microbiology)	Reporting units	UKAS accreditation for purified waters	BS ISO 13959:2014 max. limits	Notes derived from RA/ART clinical practice guidelines
RATM	ENDOTOX	Bacterial endotoxin	0.01 - 1.0	EU/ml	Yes	0.25 EU/ml	Test at least monthly (action limit at 50% max limits)
	TVC_06	Total viable count @ 22°C/7 days	0 - 100,000	cfu/100 ml	Yes	100 cfu/ml	
n/a	Chlorine03	Chlorine, total	0.02	mg/l	No	0.1 mg/l	At least weekly, to be performed immediately after drawing sample
RA 1	Al57	Aluminium, total – purified ICPMS	0.005	mg/l	Yes	0.01 mg/l	Mandatory monitoring suite, testing every 3 months
	Ca05	Calcium, total	0.05	mg/l	No	2 mg/l	
	Fluoride01	Fluoride	0.1	mg/l	Yes	8 mg/l	
	K04	Potassium, total 0.5 mg/lz Yes 8 mg/l Mg05 Magnesium, total 0.1	0.5	mg/l	Yes	4 mg/l	
	Mg05	Magnesium, total	0.1	mg/l	No	70 mg/l	
	Na04	Sodium, total	0.1	mg/l	Yes		
	Cu04	Copper, total	0.02	mg/l	Yes	0.1 mg/l	
	Nitrate01	Nitrate as N	0.5	mg/l	Yes	2 mg/l	

Normec Latis Scientific suite	Normec Latis Scientific determinand code	Determinand	Reporting limit (chemistry) reporting range (microbiology)	Reporting units	UKAS accreditation for purified waters	BS ISO 13959:2014 max. limits	Notes derived from RA/ART clinical practice guidelines
RA 2	As57	Arsenic, total – purified ICPMS	0.001	mg/l	Yes	0.005 mg/l	In water treated by RO, these contaminants will only exceed the limits if they occur at relatively high levels in the water supplied to the unit. These contaminants can be omitted from routine tests if data is available to show that the levels in the water supplied to the unit rarely exceed the limit
	Cd57	Cadmium, total – purified ICPMS	0.001	mg/l	Yes	0.001 mg/l	
	Cr57	Chromium, total – purified ICPMS	0.001	mg/l	Yes	0.014 mg/l	
	Hg59	Mercury, total	0.025	mg/l	Yes	0.0002 mg/l	
	Pb57	Lead, total – purified ICPMS	0.001	mg/l	Yes	0.005 mg/l	
	Sulphate01	Sulphate	5	mg/l	Yes	100 mg/l	
RA 3	Ag57	Silver, total – purified ICPMS	0.002	mg/l	Yes	0.005 mg/l	Levels not specified in drinking water but not considered to occur in levels which would cause concern. Testing is only required where there is evidence of high levels in water supply
	Ba57	Barium, total – purified ICPMS	0.002	mg/l	Yes	0.1 mg/l	
	Be57	Beryllium, total – purified ICPMS	0.0002	mg/l	Yes	0.0004 mg/l	
	Tl57	Thallium, total – purified ICPMS	0.001	mg/l	Yes	0.002 mg/l	
	Zn57	Zinc, total – purified ICPMS	0.001	mg/l	Yes	0.1 mg/l	
n/a	Sb57	Antimony, total – purified ICPMS	0.001	mg/l	Yes	0.006 mg/l	Excluded from RA/RAT – limits for UK drinking water is lower than limit for dialysis water

Steam sterilisers

The quality of steam used in sterilisation will affect the longevity of the steriliser alongside the efficacy of the sterilisation process and thereby the safety of the end product.

Full steam purity testing is available for operational and performance qualification.

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	HTM 01-01 Part C Table 5 specifications
ENDOTOX	Bacterial endotoxin	0.01 - 1.0	EU/ml	Yes	<0.25 EU/ml (load)

Normec Latis Scientific determinand	Determinand	Reporting range	Units	UKAS accreditation for purified waters	HTM 01-01 Part C Table 5 specifications
Amm02	Ammoniacal nitrogen as NH_4	0.04	mg/l	Yes	<0.2 mg/l (load)
Chloride07	Chloride	0..5	mg/l	No	<0.1mg/l (corrosion), <0.5 mg/l (load)
HMETAL01	Heavy metals	0.1	mg/l	No	<0.1 mg/l (corrosion and load)
Nitrate05	Nitrate as NO_3	0.2	mg/l	Yes	<0.2 mg/l (load)
OXSUB01	Oxidisable substances	0.5	mg/l	Yes	(load)
P11	Phosphorus, total as P_2O_5	0.046	mg/l	Yes	<0.1 mg/l (corrosion and load)
RESONEVAP1	Residue on evaporation	30	mg/l	No	<30 mg/l (load)
Silicate01	Silicate, soluble	0.1	mg/l	No	<0.1 mg/l (corrosion)
Sulphate01	Sulphate	5	mg/l	Yes	(load)
Hard18	Hardness, total as $CaCO_3$	0.02	mmol/l	Yes	<0.02 mmol/l (corrosion)
EC01	Electrical conductivity @20°C	0	æS/cm	No	<3 µs/cm(corrosion), <35 µs/cm (load)
Appear01	Appearance	n/a	No	clear, colourless, no sediment (corrosion), clear and colourless (load)	
Cd04	Cadmium, total	0.005	mg/l	Yes	<0.005 mg/l (corrosion)
Pb04	Lead, total	0.01	mg/l	Yes	<0.05 mg/l (corrosion)
pH05	pH	2 - 13	pH unit	Yes	5 - 7 (corrosion)
Ca05	Calcium, total	0.05	mg/l	No	(load)
Mg05	Magnesium, total	0.1	mg/l	No	(load)

Mycobacteria testing by qPCR

We offer UKAS-accredited detection and real-time quantification of *Mycobacterium* species in purified waters used in clinical settings. This enables the risk of infection generated by mycobacteria to be managed.

Our mycobacterial testing can be done via qPCR with results being issued within 48 hours.

This compares to up to 6 weeks when using the culture method for *M. chimaera* detection.

The fast turnaround allows equipment to stay up and running and decisions to be made quickly and accurately.

We're also able offer speciation for three main species of concern (*M. abscessus, M. avium*, and *M. chimaera*), allowing clinical settings to prioritise remedial action effectively. While we can test for any combination of these species as required from water samples, we can even perform such testing on positive samples from culture.

Bottle and sample volume requirements:
Based on the technical guidance and market information, we recommend a standard 1 litre plastic bottle as a minimum. Bottles should contain 18mg/l of sodium thiosulphate.

Heater-cooler units

An environmental sampling protocol for heater-cooler units was issued by Public Health England (PHE) following a series of investigations which revealed a small risk of *Mycobacterium chimaera* infection in patients following cardiac surgery.

This has been attributed to contaminated water from heater-cooler units being transmitted as aerosols during cardiothoracic surgery, where the device is utilised as part of the cardiopulmonary bypass equipment.

Environmental mycobacteria

Normec Latis Scientific holds UKAS accreditation for the testing of mycobacteria in purified waters.

The current method (MIC018a) utilises a solid medium plate of Middlebrook 7H10 following the Department of Health's Technical Memorandum HTM 01-06, 2016.

Normec Latis Scientific will, if requested, arrange for positive environmental mycobacteria isolates to be retained for speciation and identification of specific species such as *Mycobacterium chimaera, M. avium* and *M. abscessus.*

Additional testing for heater – cooler units

Additional testing offered for heater cooling units include: *Legionella pneumophila* & other *Legionella* species; *Pseudomonas aeruginosa*; Total viable count @ 22°C/72 hours and @ 37°C/ 48 hours; and mould analysis.

Heater-cooler units

Legionella

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for process waters
LEGIOND1	Other *Legionella* species	50 - 15,000	cfu/vol	Yes
LEGIOND2	*Legionella pneumophila* SG 1	50 - 15,000	cfu/vol	Yes
LEGIOND3	*Legionella pneumophila* SG 2-14	50 - 15,000	cfu/vol	Yes

Pseudomonas aeruginosa

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for process waters
P_AERU5	*Pseudomonas aeruginosa* (250 ml)	0 - 100	cfu/250 ml	Yes

Environmental mycobacteria

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for process waters
ENV_MYCO14	Environmental mycobacteria	0 - 100	cfu/100 ml	N

Total viable count (colony count)

Normec Latis Scientific determinand	Determinand	Reporting range	Units	UKAS accreditation for process waters
TVC_01	Total viable count @ 22°C/72 hours	0 - 15,000	cfu/ml	Yes
TVC_02	Total viable count @ 22°C/72 hours	0 - 15,000	cfu/ml	Yes

Mould

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for process waters
MOULD2	Mould	0 - 100	cfu/100 ml	No

Detection of multi-drug-resistant pathogens

We've developed analytical methodologies to identify two highly-prevalent and potentially life-threatening emerging nosocomial pathogens listed below. However, please enquire if you have a specific interest in the detection of other pathogens. We are constantly expanding our capabilities.

Our method is based on membrane filtration, combining procedures from the Standing Committee of Analysts and international standards with a validated chromogenic medium specific to this species of bacteria.

Stenotrophomonas maltophilia and *Acinetobacter* spp. are potentially life-threatening pathogens, particularly in healthcare settings. They are often resistant to many antibiotics and can be found in soil, water and in the hospital environment.

Stenotrophomonas maltophilia

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for process waters
STENO01	*Stenotrophomonas maltophilia*	0 - 100 (upper limit can be increased if desired)	cfu/100 ml	No

Acinetobacter species

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for process waters
ACINET01	*Acinetobacter spp.*	0 - 100 (upper limit can be increased if desired)	cfu/100 ml	No
ACINET02	Speciation of *Acinetobacter spp.*	n/a	n/a	No

Antimicrobial resistance (AMR) testing

With increasing importance placed on antimicrobial resistance and its growing problem, as well as the WHO's crisis action plan, we have developed analytical methodologies to identify resistant bacteria within the laboratory, with results provided within 2 working days dependent on organism growth times.

We have various methods based on membrane filtration, combining procedures from the Standing Committee of Analysts and international standards with fully validated media.

Normec Latis Scientific determinand code	Determinand examples	Reporting limit	Units	Suitable water matrices	UKAS accreditation
Various	CRE (Carbapenemase-resistant Entero-bacteriaceae) MRSA (Methicillin-resistant *Staphylococcus aureus*) ESBL (Extended-spectrum beta-lactamase-producing bacteria) VRE (Vancomycin-resistant enterococci)	0 .- 100	cfu/100 ml	Potable Purified Process Wastewater Others	No

In addition to the above, various other more bespoke tests are available for the unique scenarios that you may encounter. If chromogenic media are not available for this 48-hour-to-report test, we have capabilities to conduct antimicrobial sensitivities for all Cat 1 & 2 culturable bacteria using EUCAST guidelines.

New product validation and efficacy testing

We offer microbiological validation and efficacy testing for the backing of new or improved product claims. This service will support our customers in obtaining evidence for approval by numerous regulatory bodies such as FDA and MHRA. Our service goes beyond analytical testing as we'll also provide a full report that includes the methodologies used in the project and its findings. Your project will be assigned to a technical manager who will be available to guide you through your product validation journey.

Contact us for further details.

Bioburden and sterility testing

Sterility testing is a quality control process used in healthcare settings to verify efficacy of cleaning processes, ensuring the introduction of contaminants is prevented and contamination risks reduced.

Bioburden testing is similar to sterility however instead it identifies and quantifies viable microorganisms on a medical device before it is sterilised.

We've developed analytical methods which are based on The Sterilisation of Healthcare Products: BS EN ISO 11737-1:2019 for bioburden testing and BS EN ISO 11737-2:2019 for sterility testing.

Our sterility and bioburden testing is an extension to our medical device analytical capability. Both methods are UKAS-accredited.

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation	Satisfactory results HTM 04-01
TVC_20	Bioburden @ 35°C – 72hrs	0 - 100	cfu/instrument	Yes	Not detected
STERL1	Sterility	Growth / no growth	n/a	Yes	Not detected

Potable water systems

Healthcare premises

Pipework supplying potable water within healthcare premises is often large and complex, and comprehensive management of the system is necessary to control waterborne pathogens. As well as compliance to the HSE's Approved Code of Practice and guidance on regulations 'Legionnaires' disease: The control of *Legionella* bacteria in water systems (L8)', particular significance is placed within HTM 04-01 on the control of *Pseudomonas aeruginosa* in augmented care units.

Pseudomonas aeruginosa is an opportunistic pathogen capable of infecting vulnerable patients and has been shown to readily colonise systems and outlets without proper management and surveillance.

Normec Latis Scientific offers two UKAS accredited methods available for the detection of *Pseudomonas aeruginosa*. One is the culture method as specified in HTM 04-01 Part B Appendix F and based on 'Microbiology of drinking water – Part 8: the isolation and enumeration of *Aeromonas* and *Pseudomonas aeruginosa*.

In the second method, results are available after 24 hours as a confirmed positive. The method has been validated using BSEN ISO 17994 and shown to have comparable sensitivity and specificity to the culture test. This test is based on 'Microbiology of drinking water – Part 8: the isolation and enumeration of *Aeromonas* and *Pseudomonas aeruginosa'* Method C.

Retention of positive isolates can be arranged upon request and ranges can be adjusted as required with suitable dilutions.

Normec Latis Scientific determinand code	Determinand	Reporting range	Units	UKAS accreditation for potable waters	Satisfactory results HTM 04-01
P_AERU1	*Pseudomonas aeruginosa* (culture)	0 - 100	cfu/100 ml	Yes	Not detected
P_AERU6	*Pseudomonas aeruginosa* (IDEXX)	0 - 201	MPN/ 100 ml	Yes	Not detected

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