Healthcare Advanced guide

Latis Scientific is a leading provider of laboratory services for the healthcare sector and is part of the SUEZ Group

LATIS SCIENTIFIC

SUEZ

CONTENTS

Our UKAS accredited laboratory offers a high quality, tailored service for sterile services departments, medical device manufacturers and service contractors.

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

You'll also have direct access to our laboratory technical manager via a dedicated Healthcare Advanced phone number who will be on hand to answer any questions you may have to help you assess next steps.

We'll take ownership of your request, issue or question so it can be resolved promptly and efficiently.

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-disinfector

Latis determinant code	Determinand	Reporting limit	Units	UKAS accreditation for purified waters	Max. permitted values 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 @ 25øC	5	µs/cm	No	30
Hard01	Hardness, total as CaCO3	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 P2O5	0.046	mg/l	Yes	0.2
Solids24	Total dissolved solids - meter from EC 25C	5	mg/l	No	40

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	Max. permitted values for rinse water (HTM 01-01 part D)
TVC_17	Total viable count @ 35øC (average from duplicate)	0 - 100	CFU/100ml	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.

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 such as ice packs, gloves, aprons, and syringes.

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

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 lab within all UKAS set parameters to give truly representative results. Kits provided in line with HTM01-06, ISO 15883, WHTM 01-06.

- Disinfection efficacy surrogates
- Self-disinfection surrogates
- Test soils
- Pre-labelled bottles
- Consumables (gloves, syringes etc.)
- Validation kits delivered/collected from site

Weekly water testing

Oxidase testing is carried out where the weekly bacterial count is greater than 10cfu/100ml 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)

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	Satisfactory results HTM 01-06
TVC_28	Total viable count @ 30øC	0 - 100	CFU/100ml	Yes	<10

Latis determinant code	Determinand	Reporting limits	Units	UKAS accreditation for process waters	Satisfactory results HTM 01-06
EC02	Electrical conductivity @ 25øC	5	µs/cm	No	<40
Hard01	Hardness, total as CaC03	10	mg/l	Yes	<50

Quarterly water testing

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	Satisfactory results HTM 01-06
Appear01	Appearance	n/a	n/a	No	Clear, bright and colourless
EC02	Electrical conductivity @ 25øC	5	µs/cm	No	40
Hard01	Hardness, total as CaCO3	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

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for purified waters	Satisfactory results HTM 01-06
TVC_28	Total viable count @ 30øC	0 - 100	CFU/100ml	Yes	10
P_AERU1	Pseudomonas aeruginosa	0 - 100	CFU/100ml	No	Not detected
ENV_MYC014	Environmental mycobacteria	0 - 100	CFU/100ml	Yes	Not detected

Cleaning efficacy test soils

Test soil used to demonstrate cleaning efficacy is made according to ISO 15883-5 Annex R. 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 your requirements.

Endoscope storage cabinets provide a controlled environment where decontaminated endoscopes can be stored safely without being re-contaminated.

Sample kits for storage cabinets are delivered to site with all necessary consumables and pre-registered for your convenience.

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. We can arrange for contact plate kits to be delivered to, and collected from site.

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for purified waters
DryCCBac_1	Bacterial count @ 30C/5 days	0 - 100	CFU/plate	Yes
DryCCFun_1	Fungal count @ 30C/5 days	0 - 100	CFU/plate	Yes
DryCCTVC_1	Total viable count @ 30C/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.

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for purified waters
DryCFun_2	Fungal count @ 30C/ 5 days (endoscope)	0 - 100	CFU/endoscope surrogate	No
DryCTotal	Total viable count @ 30C/5 days (endoscope)	0 - 200	CFU/endoscope surrogate	No
DryCTVC_2	Bacterial count @ 30C/5 days (endoscope)	0 - 100	CFU/endoscope surrogate	No

Air plates

Airborne microbial contamination is evaluated using either active sampling air plates or sedimentation plates.

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for purified waters
DryCCBac_1	Bacterial count @ 30C/5 days	0 - 100	CFU/plate	Yes
DryCCFun_1	Fungal count @ 30C/5 days	0 - 100	CFU/plate	Yes
DryCCTVC_1	Total viable count @ 30C/5 days (plate)	0 - 100	CFU/plate	Yes

Healthcare Advanced - Renal dialysis

Patients going through dialysis treatments are exposed to a large volume of water through the treatment. As such, ensuring the quality of dialysis water is essential. Latis Scientific offers dialysis water quality testing according to the Clinical Practice Guidelines by the UK Renal Association and Association of Renal Technologists.

Latis suite	Latis determinant code	Determinant	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 @ 22øC/7 days	0 - 100,000	CFU/100ml	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	0.2 mg/l	
	K04	Potassium, total	0.5	mg/l	Yes	8 mg/l	
	Mg05	Magnesium, total	0.1	mg/l	No	4 mg/l	
	Na04	Sodium, total	0.1	mg/l	Yes	70 mg/l	
	Cu04	Copper, total	0.02	mg/l	Yes	0.1 mg/l	
	Nitrate01	Nitrate as N	0.5	mg/l	Yes	2 mg/l	
RA2	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	µg/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

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.

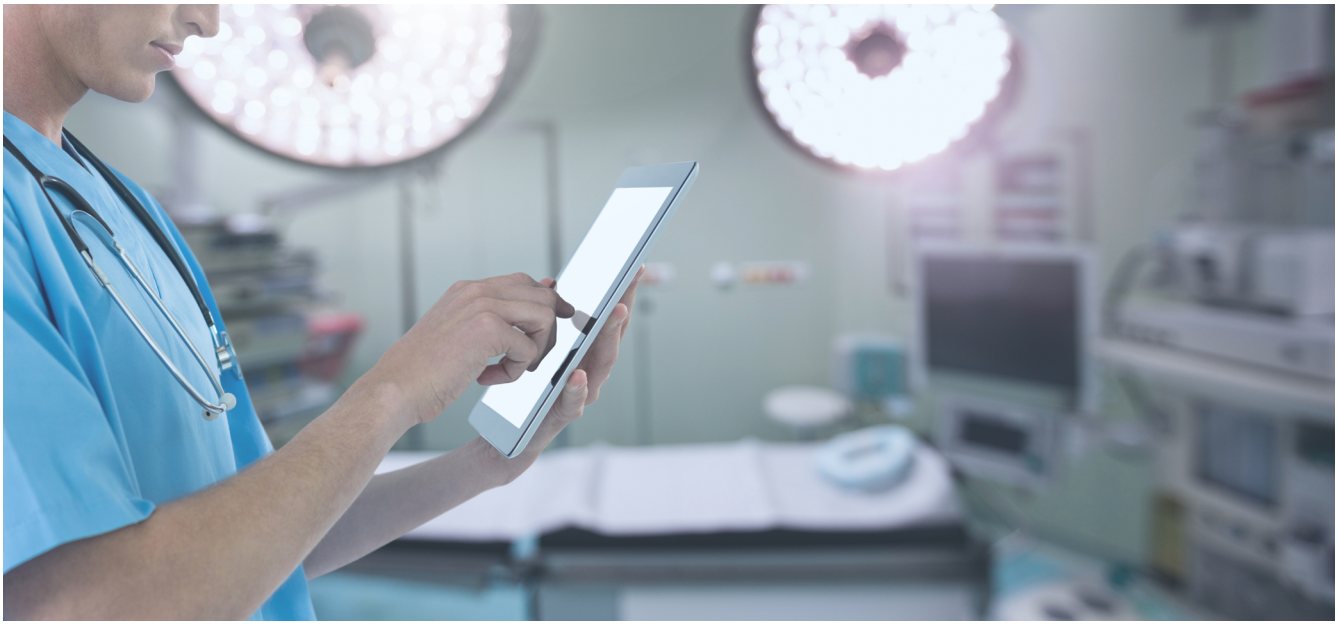
Full steam purity testing is available for operational and performance qualification.

Latis determinant 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)

Latis determinant code	Determinand	Reporting limits	Units	UKAS accreditation for purified waters	HTM 01-01 Part C Table 5 specifications
Amm02	Ammoniacal nitrogen as NH4	0.04	mg/l	Yes	<0.2 mg/l (load)
Chloride07	Chloride	0.5	mg/l	No	<0.1 mg/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 NO3	0.2	mg/l	Yes	<0.2 mg/l (load)
OXSUB01	Oxidisable substances	0.5	mg/l	Yes	(load)
P11	Phosphorus, total as P2O5	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 CaCO3	0.02	mmol/l	Yes	<0.02 mmol/l (corrosion)
EC01	Electrical conductivity @ 20øC	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)

An environmental sampling protocol for heater-cooler units was issued by Public Health England (PHE) following a series of investigation 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.



Air sampling

Our trained consultancy staff offer air sampling of theatres following the procedure outlined in Environmental Sampling, Processing and Culturing of Water and Air Samples for the Isolation of Slow-Growing Mycobacteria; Public Health England, July 2016. Please contact us for details of the test.

Water sampling/testing

Latis Scientific offers testing of water taken from the heater cooler unit. Our consultancy team offer a sampling service, but samples can also be submitted to site.

Environmental mycobacteria

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 01-06, 2016.

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.

Legionella

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for process waters
LEGIOND1	Other legionella species	50 - 15000	CFU/Vol	Yes
LEGIOND2	Legionella pneumophila SG 1	50 - 15000	CFU/Vol	Yes
LEGIOND3	Legionella pneumophila SG 2-14	50 - 15000	CFU/Vol	Yes

Pseudomonas aeruginosa

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for process waters
P_AERU5	Pseudomonas aeruginosa (250ml)	0 - 100	CFU/250ml	Yes

Total viable count (colony count)

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for process waters
TVC_01	Total viable count @ 22°C/72hrs	0 - 15000	CFU/ml	Yes
TVC_02	Total viable count @ 37°C/48hrs	0 - 15000	CFU/ml	Yes

Mould

Latis determinant code	Determinand	Reporting range	Units	UKAS accreditation for process waters
MOULD2	Mould	0 - 100	CFU/100ml	No

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.

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'. This is a standard test for Pseudomonas aeruginosa and provides a result within 2 days (+1 day where confirmation of a presumptive positive is required).

Other microbiological test suites are available depending on the particular site concerns.

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.

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

Although every effort is made to ensure the accuracy of published information in this document, the information may inadvertently contain inaccuracies or typographical errors. Every effort has been made to present you with the most accurate information of the testing we provide, but because scientific and business research is constantly evolving, we cannot be held responsible for the accuracy of our content. Latis Scientific will not be held liable and shall not accept any liability for the content or interpretation of this document and reserves the right to change the document with no prior notice.

For more information contact:

Matthew Taylor
matthew.taylor@suez.com

Latis Scientific
Unit C1, Acorn Industrial Estate, Crayford Road
Crayford, Kent, DA1 4AL

www.suez.com/en/uk/environmental-monitoring/clinical-healthcare-analysis

LATIS SCIENTIFIC

suez