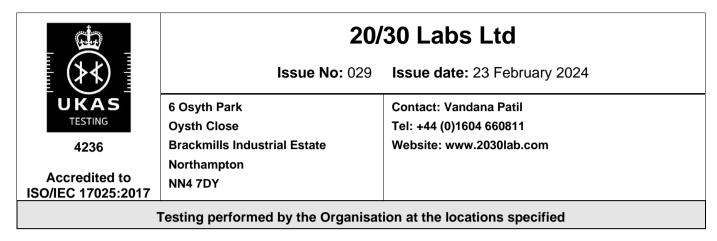
# **Schedule of Accreditation**

issued by

**United Kingdom Accreditation Service** 

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK



## Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details		Activity	Location code
Address 6 Osyth Park Oysth Close Brackmills Industrial Estate Northampton NN4 7DY	<b>Local contact</b> Vandana Patil	Testing: Microbiological & Molecular	L

### Site activities performed away from the locations listed above:

Location details	Activity	Location code
Controlled clean rooms and endoscope storage cabinets	Testing air quality for physical quality at clients premises	Site

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4236	Issue No: 029 Issue date: 23 February 2024
Accredited to	
ISO/IEC 17025:2017	
	Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WASTEWATERS	Molecular Tests		
Untreated sewage waters	Detection of SARS-CoV-2 virus RNA (N1 gene sequence only)	In house method SOP L106 Extraction: 20/30 Viral Magbead nucleic acid extraction and purification reagents Detection: Promega GoTaq Wastewater PCR assay kit using Techne	L
WATERS	Microbiological Tests	Prime Pro 48 Thermocycler Documented In-House methods:	
Sterilox Rinse Waters, Washer Disinfector Final Rinse Waters (Mains fed and Reverse Osmosis), Reverse Osmosis Water, Renal Dialysis Waters, Steam Condensates and Potable Waters	Bacterial Endotoxin levels [EU/ml]	1) L013 chromogenic LAL assay using Charles River PTS or nexgen-PTS Kinetic Reader, and Endosafe cartridges, based on HTM 2030 1997 (withdrawn), Section 9.201 to 9.212 and BS EN ISO 15883-1:2009, 6.4.2.3	L
		2) L043 kinetic turbidity LAL assay using the Charles River BioTek Reader Test System and Endoscan V software based on HTM 2030:1997 (withdrawn) section 9.201 to 9.212, BS EN ISO 15883-1:2009 6.4.2.3 and HTM 01-06 Part E 2016, WHTM 01-06 and NICFPP	L
	Enumeration:		
Potable, Spa and Pool waters	Coliforms and Escherichia coli	L020 using membrane filtration onto MLGA and confirmation by TNA based on The Microbiology of Drinking Water (Environment Agency), Part 4B 2016	L

## DETAIL OF ACCREDITATION

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WATERS (con'd)	Microbiological Tests (cont'd)	Documented In-House methods:	
	Enumeration (cont'd):		
Potable, Spa and Pool waters	Enterococci	L036 using membrane filtration based on The Microbiology of Drinking Water (Environment Agency), Part 5, 2012	L
Sterilox Rinse Waters, Washer Disinfector Final Rinse Waters (Mains fed and Reverse Osmosis), Reverse Osmosis and Potable Water	Environmental Mycobacteria at 30 °C for 28 days	L015 using membrane filtration onto supplemented Middlebrook 7H11 Agar and Ziehl Neelsen Stain confirmation, based on HTM 2030 1997 (withdrawn), Section 9.227, BS EN ISO 15883- 4:2018, Annex E3 and HTM 01-06 Part E 2016	L
Heater Cooler Unit Waters	Environmental Mycobacteria at 35 °C for 6-8 weeks	L015 using membrane filtration onto supplemented Middlebrook 7H11 Agar and Ziehl Neelsen Stain confirmation	L
Potable, Reverse Osmosis, Spa and Pool waters	Pseudomonas aeruginosa	L034 using membrane filtration based on The Microbiology of Drinking Water (Environment Agency), Part 8 2015 HTM 04-01 Part B Appendix F 2016 and HTM 01-06 Part E 2016	L
Potable Water, Sterilox Rinse Waters, Washer Disinfector Final Rinse Waters (Mains fed and Reverse Osmosis), Reverse Osmosis Water	Total Aerobic Colony Count [cfu/100 ml]	L012 using membrane filtration onto TSA Agar at 35 °C, based on HTM 2030 1997 (withdrawn), Section 9.223	L
Sterilox Rinse Waters, Washer Disinfector Final Rinse Waters (mains fed and reverse osmosis), Reverse Osmosis water	Total Aerobic Colony Count [cfu/100ml]	L040 using membrane filtration on to TSA at 30 °C for 5 days. Based on HTM 01-06 Part E 2016, WHTM 01-06, NICFPP and BS EN ISO 15883-1:2009, 6.4.2.4 and Annex D	L

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WATERS (cont'd)	Microbiological Tests (cont'd)	Documented In -House methods:	
Waters for the Preparation of Dialysis Fluid and Ultra- Pure Dialysis Water	Enumeration (cont'd): Total Aerobic Colony Count [cfu/ml or in the volume examined]	L041 using a) Pour plate, or b) Membrane filtration Using TGEA at 17 - 23 °C for 7 days. Based on BS ISO 23500- 3:2019	L
Potable, Spa, Swimming Pool and Hydrotherapy Pool Waters	Total Aerobic Colony Count [cfu/ml]	L016 using YEA pour plate at 22 °C and 37 °C based on The Microbiology of Drinking Water (Environment Agency) Part 7, 2020	L
Process water - cooling towers	Total Aerobic Colony count [cfu/ml]	SOP L016 using YEA pour plate at 30°C meeting the requirements of HSG 274 Part 1 2013	L
Sterilox Rinse Waters, Washer Disinfector Final Rinse Waters (Mains fed and Reverse Osmosis), Reverse Osmosis Water, Potable, Spa, Swimming Pool and Hydrotherapy Pool Waters	<i>Legionella</i> spp and confirmation of <i>Legionella pneumophila</i> type 1 and serogroup 2-14	L032 Direct plate method using membrane filtration onto GVPC agar at 36 °C, based on BS EN ISO 11731-2:2008 (withdrawn)	L
Process and Waste Waters	<i>Legionella</i> spp and confirmation of <i>Legionella pneumophila</i> type 1 and serogroup 2-14	L046 three plate method using membrane filtration onto GVPC agar at 36 °C, based on BS 6068- 4.12:1998 / ISO 17731:1998 Part 4:Section 4.12 (withdrawn)	L

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
MEDICAL DEVICES		Documented In -House methods:	
	Inoculation, recovery and enumeration of Pseudomonas aeruginosa or Staphylococcus aureus from lumened devices	L045 using inoculation technique, elution by flushing, membrane filtration onto CFC and BP agar, based on BS EN ISO 15883- 4:2018 Section 6.6.2 and Annex B, BS EN ISO 16442:2015 Annex E plus HTM2030:1997 Section 11 (withdrawn) plus HTM 01-06 Part E 2016 - Decontamination of flexible endoscopes: Testing methods sections 20.4 to 20.10	L
	Sterility Testing	L052 using TSB enrichment at 22 °C for 14 days. Based on ISO 11737-2:2020 and USP 71	L
(including biological indicators)	Recovery of Geobacillus stearothermophilus	L052 Annex A using TSB enrichment at 55 °C for 7 days	L
	Bioburden Testing	L053 using sonication in diluent, membrane filtration on to TSA at 32 °C for 7 days. Based on ISO 11737-1:2018+A1:2021	L
DISINFECTANTS, ANTISEPTICS, BIOCIDES, HANDWASHES, HANDRUBS	Microbiological Tests (cont'd)	Documented In-House methods	
	Quantitative suspension test for	L067 based on: EN 1276:2019 EN 13623:2020 EN 13624:2021 (yeasticidal activity only) EN 13704:2018 EN13727:2012+A2: 2015 EN 14348:2005 EN 14204:2012 EN 1650:2019 (yeasticidal activity only) EN 1657:2016 (yeasticidal activity only) EN 1656:2019 EN 17126:2018	L

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ENVIRONMENTAL SAMPLES	<u>Microbiological Tests</u> (cont'd) Enumeration:	Documented In-House methods	
Contact plates, settle plates, plates from air samplers, finger imprint plates	Total Aerobic Colony Count Yeasts and Moulds	L057 using TSA at 30 °C for 5 days and SDA at 22°C for 7 days. Based on BS EN ISO 17141:2020, BS EN ISO 16442:2015 Section 6.5 and Annex C	L
Swabs	Total Aerobic Colony Count	L058 using membrane filtration on to TSA at 30 °C for 5 days. Based on BS EN ISO 17141:2020, BS EN ISO 16442:2015 Annex B1 and B2	L
	Physical Tests		
Controlled clean rooms and endoscope storage cabinets	Particle Counting for Classification and Monitoring of air cleanliness	L055 based on BS EN ISO 14644- 1:2015 and current GMP Practice	Site
END			