


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO/IEC 17025:2005	20/30 Labs Ltd	
	Issue No: 016 Issue date: 12 December 2018	
	6 Osyth Park Oyth Close Brackmills Industrial Estate Northampton NN4 7DY	Contact: Meredith Smart Tel: +44 (0)1604 660811 Website: www.2030lab.com
Testing performed by the Organisation at the locations specified		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address 6 Osyth Park Oyth Close Brackmills Industrial Estate Northampton NN4 7DY	Local contact Meredith Smart	Testing: Microbiological	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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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>WATERS</p> <p>Sterilox Rinse Waters, Washer Disinfectant Final Rinse Waters (Mains fed and Reverse Osmosis), Reverse Osmosis Water, Renal Dialysis Waters, Steam Condensates and Potable Waters</p>	<p><u>Microbiological Tests</u></p> <p>Bacterial Endotoxin levels [EU/ml]</p>	<p>Documented In-House methods:</p> <p>1) L013 chromogenic LAL assay using Charles River Portable Test System (PTS) Kinetic Reader, and Endosafe cartridges, based on HTM 2030 1997 (withdrawn), Section 9.201 to 9.212 and BS EN ISO 15883-1:2009, 6.4.2.3</p> <p>2) L043 kinetic turbidity LAL assay using the Charles River Tecan Sunrise Microplate Reader Test System and Endoscan V software based on HTM 2030:1997 (withdrawn) section 9.201 to 9.212, BS EN ISO 15883-1:2009 6.4.2.3 and HTM 01-06 Part E 2016, WHTM 01-06 and NICFPP</p>	L
<p>Potable, Spa and Pool waters</p>	<p>Enumeration:</p> <p>Coliforms and <i>E.coli</i></p>	<p>L020 using membrane filtration onto MLGA and confirmation by TNA based on The Microbiology of Drinking Water (Environment Agency), Part 4B 2016</p>	L
<p>Potable, Spa and Pool waters</p>	<p>Enterococci</p>	<p>L036 using membrane filtration based on The Microbiology of Drinking Water (Environment Agency), Part 5, 2012</p>	L



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WATERS (cont'd)	<u>Microbiological Tests</u> (cont'd)	Documented In -House methods:	
	Enumeration: (cont'd)		
Sterilox Rinse Waters, Washer Disinfectant Final Rinse Waters (Mains fed and Reverse Osmosis), Reverse Osmosis Water and Potable Water	Environmental Mycobacteria [cfu/100 ml]	L015 using membrane filtration onto supplemented Middlebrook 7H11 Agar at 30 °C and Ziehl Neelsen Stain confirmation, based on HTM 2030 1997 (withdrawn), Section 9.227, BS EN ISO 15883-4:2009, Annex E3 and HTM 01-06 Part E 2016	L
Potable, Reverse Osmosis, Spa and Pool waters	<i>Pseudomonas aeruginosa</i>	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 Disinfectant 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 Disinfectant 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
Waters for the Preparation of Dialysis Fluid and Ultra-Pure Dialysis Water	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 13959:2014 and BS ISO 23500:2014	L



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WATERS (cont'd)	<u>Microbiological Tests</u> (cont'd)	Documented In -House methods:	
Potable, Spa, Swimming Pool and Hydrotherapy Pool Waters	Enumeration: (cont'd) 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, 2012	L
Sterilox Rinse Waters, Washer Disinfectant Final Rinse Waters (Mains fed and Reverse Osmosis), Reverse Osmosis Water, Potable, Spa, Swimming Pool and Hydrotherapy Pool Waters	Detection and Enumeration: <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	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	L
Endoscope Surrogate Devices and Lumened Medical Devices	Inoculation, recovery and enumeration of <i>Pseudomonas aeruginosa</i> or <i>Staphylococcus aureus</i> from lumened devices	L045 using inoculation technique, elution by flushing, membrane filtration onto CFC and BP agar, based on BS EN ISO 15883-4:2009 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
Medical Devices	Sterility Testing	L052 using TSB enrichment at 22 °C for 14 days. Based on ISO 11737-2:2009 and USP 71	L



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Medical Devices	<u>Microbiological Tests</u> (cont'd) Bioburden Testing	Documented In-House methods (cont'd): L053 using sonication in diluent, membrane filtration on to TSA at 32 °C for 7 days. Based on ISO 11737-1:2017	L
DISINFECTANTS, ANTISEPTICS, BIOCIDES, HANDWASHES, HANDRUBS	Bacterial quantitative suspension test for medical applications	L067 based on BS EN 13727:2012 +A2:2015	L
Environmental Samples: Contact plates, settle plates, plates from air samplers, finger imprint plates	<u>Microbiological Tests</u> Enumeration of: 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 14698-1:2003, 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 14698-1:2003, BS EN ISO 16442:2015 Annex B1 and B2	L
Controlled clean rooms and endoscope storage cabinets	<u>Physical Tests</u> Particle Counting for Classification and Monitoring of air cleanliness	L055 based on BS EN ISO 14644-2:2015 and current GMP Practice	Site
END			