Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



4147

Accredited to ISO/IEC 17025:2017

ML4 3NJ

Andersen Caledonia Ltd

Issue No: 033 Issue date: 19 January 2024

Caledonian House Contact: Mrs C Walsh
Phoenix Crescent Tel: +44 (0)1698 844476
Strathclyde Business Park Fax: +44 (0)1698 844481

Bellshill E-Mail: cwalsh@andersencaledonia.co.uk
Lanarkshire Website: www.andersencaledonia.com

Testing performed by the Organisation at the locations specified

Locations covered by the organisation and their relevant activities

Location details		Activity	Location code
Bellshill Phoenix Crescent Strathclyde Business Park Bellshill ML4 3NJ	Local contact Claire Walsh 01698 844 476	Testing Activities: Water testing, Environmental testing and Medical Device testing	A
Dunston Barn 7, Office 1B Dunston Business Village Stafford Road Dunston ST18 9AB	Local contact Ronan Stapleton 01785711588	Testing Activities: Water testing, Environmental testing	В
Customer Premises Clean Rooms and other associated controlled environments		Testing Activities: Active Air Monitoring	С

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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
WATERS	Microbiological Tests	Documented In-house Methods	
	Enumeration of:		
Potable waters, domestic waters,	Total Aerobic Colony Count	Method No 4173 using pour plate on YEA at 22 °C 68 ± 4 h and 37 °C 44 ± 4h based on MDW, Part 7, 2020	A
Potable water, Domestic water, Pool and Spa Water	Total Aerobic Colony Count	Method No 4173 using spread plate onto YEA at 22 °C for 68 ± 4h and 37 °C for 44 ± 4h based on MDW Part 7, 2020	А
Potable waters	Total Aerobic Colony Count	Method No 4173 using spread plate onto YEA at 22 °C for 68 ± 4h and 37 °C for 44 ± 4h based on MDW Part 7, 2020	В
Potable waters, domestic waters, pools and spa waters	Coliform (confirmed)	Method No 4216 based on MDW, Part 4b, (2016) using membrane filtration onto MLGA at 30 °C for 4 ± 0.25h then 37 °C for minimum 14h	A
Potable waters	Coliform (confirmed)	Method No 4216 based on MDW, Part 4b, (2016) using membrane filtration onto MLGA at 30 °C for 4 ± 0.25h then 37 °C for minimum 14h	В
Potable waters, domestic waters, pools and spa waters	Escherichia coli (confirmed)	Method No 4216 based on MDW, Part 4b, (2016) using membrane filtration onto MLGA at 30 °C for 4 ± 0.25h then 37 °C for minimum 14h	A
Potable waters	Escherichia coli (confirmed)	Method No 4216 based on MDW, Part 4b, (2016) using membrane filtration onto MLGA at 30 °C for 4 ± 0.25h then 37 °C for minimum 14h	В

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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)	Micorbiological Tests (cont'd)	Documented In-house Methods	
	Enumeration of: (cont'd)		
Potable waters, hospital washer disinfectors, pools and spa waters	Pseudomonas aeruginosa (confirmed)	Method No 4213 based on MDW, Part 8, 2015 using CN plates onto membrane filtration at 37 °C for 44 ± 4h	А
Potable waters	Pseudomonas aeruginosa (confirmed)	Method No 4213 based on MDW, Part 8, 2015 using CN plates and membrane filtration at 37 °C for 44 ± 4h	В
AER Final Rinse Water	Total Viable Count of Water	Method No 4301 using R2A medium by Membrane Filtration based on HTM 01- 06 Part E	А
Rinse water (hospital washer disinfectors)	Total Aerobic Colony Count	In-House Method No 4114 by membrane filtration and TSA at, 35 °C/3 days based on HTM 2030 (withdrawn)	А
Potable waters, domestic waters, pool and spa waters	Total Aerobic Colony Count	In-House Method No 4173 using YEA, pour plate, 37 °C for 24h	А
AER waters	Total Aerobic Colony Count	Method 4301 based on HTM01-06 Part E, WHTM 01-06 Part E & BS EN ISO 15883-4 using R2A and membrane filtration at 30 °C for 5 days	В
Reverse Osmosis waters	Total Aerobic Colony Count	Method 4380 based on HTM01-01 Part D using TSA and membrane filtration at 37 °C for 2 days and 22 °C for 3 days	В
Washer Disinfector Final Rinse Waters (fed by reverse osmosis supply), Reverse Osmosis water AER Final Rinse Water	Environmental Mycobacteria	Method 4229 using membrane filtration onto supplemented Middlebrook 7H10 Agar at 30 °C and Ziehl Neelsen Stain confirmation, based BS EN ISO 15883-4:2018, Annex E3, HTM 01-06 Part E, WHTM 01-06 Part E and HTM 2030 (withdrawn)	A, B

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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)	Micorbiological Tests (cont'd)	Documented In-house Methods	
	Enumeration of: (cont'd)		
Medical Devices Instruments and Bowls	Bioburden Testing	Method 4141 using agitation Extraction in diluent with membrane filtration on to TSA at 35 °C for 3 days for Bacteria and Endospores, SDA at 22 °C for 5 days for Fungi. Based on ISO 11737-1:2018	А
Inoculated Surrogate Devices – Washer Disinfectors	Recovery & Enumeration of inoculated surrogates - Ps. aeruginosa, S. aureus, B. subtillis & C. albicans	Method 4312G based on BS EN ISO, 15883-4:2018, HTM 01-06 Parts D & E, WHTM 01-06 Parts D & E - using CN plates at at 37 °C for 48h (<i>Ps. aeruginosa</i>), BP plates at 37 °C for 48h (<i>S. aureus</i>), TSA plates at 37 °C for 24h (<i>B. subtillis</i>) & SDA plates at 37 °C for 5 days (<i>C. albicans</i>)	А, В
Sterile Surrogate Devices – Endoscope Storage Cabinet & Endoscope Drying Cabinet	Recovery & Enumerations (TVC) of Sterile Surrogate Devices	Method 4312 section 6.2 based on BS EN 16442:2015 using 90mm TSA plates at 30 °C for 3 days & 90mm SDA plates at 30 °C for 5 days	A, B
Steam condensate, RO, AER and Final Rinse water	Endotoxin	Method 4378 Turbidimetric assay using the Associates of Cape Cod, Pyros Kinetix Flex PKF96 System to meet HTM01-01 Part C and D	В
Medical Devices	Endotoxin	Method 4081 by Gel Clot based on United States Pharmacopeia <85> and United States Pharmacopeia <161>	А
	Detection and Enumeration of:		
Hot and Cold Water supply systems, Potable waters (non- regulatory)	Legionella spp. including identification of: L. pneumophila serogroup 1 and L. pneumophila serogroup 2-14	Method 4028 based on BS EN ISO 11731:2017 using filtration with washing, identification by latex agglutination using the Oxoid DR 0800M Latex Kit [Matrix A, Procedure 8,9 and 10. Media A and C]	В

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	Type of test/Properties	Standard specifications/	Location
Materials/Products tested	measured/Range of measurement	Equipment/Techniques used	Location Code
WATERS (cont'd)	Molecular Detection		
Reverse Osmosis and Process Waters	Mycobacterium species Target DNA sequence 16S rRNA Gene Sequence	Method No 4384 using Membrane filtration, recovery of Mycobacterium into 2.0ml wash buffer, DNA Extraction / Immuno magnetic Purification with Detection using Genesig Q16 qPCR Thermocycler using the Primer Design Genesig Easy Detection qPCR Assay kit	В
	Chemical and Physical Tests	Documented In-house Methods	
Reverse Osmosis, Clean/Purified water, potable water (non-regulatory)	рН	Method 22009 using Mettler Toledo pH Meter, based on HTM 01-01 Parts C and D	В
Reverse Osmosis, Clean/Purified water	Total organic carbon	Method 22013 using Beckman Coulter TOC Analyser, based on HTM 01-06 Part E	В
ENVIRONMENTAL SAMPLES	Microbiological Tests	Documented In-house Methods	
SAMPLES	Environmental settle plates	1) Method 4381 based on BS EN 16442:2015 using 90mm TSA plates at 30 °C for 5 days	В
		2) Method 4008 based on BS EN 17141:2020 using 90mm TSA plates at 35 °C for 3 days & 90mm SDA plates at 22 °C for 5 days	A, B
		3) Method 4381 based on BS EN 16442:2015 using 55mm TSA plates at 30 °C for 5 days	В
		4) Method 4010 based on, BS EN 17141:2020 using 55mm TSA plates at 35 °C for 3 days & 55mm SDA plates at 22 °C for 5 days	А, В

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ENVIRONMENTAL SAMPLES (cont'd)	Physical tests		
Customer Clean Rooms and associated Controlled Environments	Air monitoring of Biological Air Quality	Procedure 4018 based on BS EN ISO 17141:2020, ISO 14644-1:2015 and ISO 14644-2:2015 using ORUM Trio Bas Duo Air Sampler. Plates handled as follows: TSA incubated at 35 °C for 72 hours SDA incubated at 22°C for 120 hours	С
END			

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