



Purified (Reagent) Water Specification Testing Results (Ohio Facility)

For the month of: April 2016 (H16092-H16121)

Listed below are the testing results for the purified water used in the manufacture of products at Hardy Diagnostics.

Test	Testing Frequency	Units	In-House Specification (method detection limit)	Testing Data
Minimum Resistivity* ^{1,3,4,5}	Continuous Monitoring	Megohm cm	> 16.0	17.74
pH**	Daily	N/A	5.5 – 7.5	7.21
Total Organic Carbon ^{1,3,5}	Monthly	µg/L	<500	187
Heavy Metals (Single) ^{1,3,4} (Cd, Cr, Cu, Ni, Pb and Zn)	Annually	mg/L	< 0.05	Cd – ND Cr – ND Cu – 0.0031 Pb – 0.0013 Ni – ND Zn – ND
Heavy Metals (Total) ^{3,4}	Annually	mg/L	< 0.1	0.0082
Ammonia/Organic Nitrogen ³	Monthly	mg/L	< 0.1	ND
Total Chlorine Residual ^{3,4}	Monthly	mg/L	<0.1	<0.1
Maximum Bacterial Content*** ^{1,3,4,5}	Weekly	colony forming units (CFU) per milliliter	<10	<0.1
Water Quality ^{3,4} ratio	Annually	ratio	0.8 – 3.0	1.03
Use Test (Student <i>t</i>) ³	Quarterly	N/A	≤ 2.78	≤ 2.78
Inhibitory Residue ⁴	Annually	N/A	< 15%	-1.4%
Maximum Silicate, SiO ₂ ^{3,4}	Annually	mg/L	≤ 0.05	ND

ND = Not Detected at or above the method detection limit.

*Testing data is given as a monthly average at the water source.

**Testing data is given as a monthly average.

***Testing data is given as an average.

References:

1. *Preparation and Testing of Reagent Water in the Clinical Laboratory*, C3-A4. Clinical Laboratory Standards (CLSI), Villanova, PA.
2. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22-A3. Clinical Laboratory Standards Institute (CLSI – formerly NCCLS), Villanova, PA.
3. American Public Health Association, *Standard Methods for the Examination of Water and Wastewater*, Washington, D.C.
4. *Manual for the Certification of Laboratories Analyzing Drinking Water*, Criteria and Procedures Quality Assurance, Environmental Protection Agency (EPA).
5. USP. *USP-NF, Water for Pharmaceutical Purposes <1231>*. Rockville, MD: US Pharmacopeial Convention.

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