



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

For the month of: January 2021

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	18.51
pH**	Daily	N/A	5.5 – 7.5	6.06
Total Organic Carbon 1,3,5	Monthly	µg/L	< 500	ND
Heavy Metals (Single) 1,3,4 (Cd, Cr, Cu, Ni, Pb and Zn)	Annually	mg/L	< 0.05	Cd – ND Cr – ND Cu – ND Pb – ND Ni – ND Zn – ND
Heavy Metals (Total) 3,4	Annually	mg/L	< 0.1	ND
Ammonia/Organic Nitrogen 3	Monthly	mg/L	< 0.1	ND
Total Chlorine Residual 3,4	Monthly	mg/L	< 0.1	ND
Maximum Bacterial Content*** 1,3,4,5	Weekly	colony forming units (CFU) per milliliter	< 10	< 1.0
Water Quality 3,4 ratio	Annually	ratio	0.8 – 3.0	0.96
Use Test (Student t) 3	Quarterly	N/A	≤ 2.78	≤ 2.78
Inhibitory Residue 4	Annually	N/A	< 15%	10.5%
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.

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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.

Andre Hsiung
Director of Technical Services

Hardy Diagnostics
1430 W. McCoy Lane
Santa Maria, CA 93455
(800) 266-2222
www.hardydiagnostics.com