



**Purified (Reagent) Water Specification Testing Results (Ohio Facility)**  
**For the month of: September 2016 (H16245-H16274)**

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* <sup>1,3,4,5</sup>	Continuous Monitoring	Megohm cm	> 16.0	17.88
pH**	Daily	N/A	5.5 – 7.5	7.25
Total Organic Carbon <sup>1,3,5</sup>	Monthly	µg/L	<500	180
Heavy Metals (Single) <sup>1,3,4</sup> (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) <sup>3,4</sup>	Annually	mg/L	< 0.1	0.0082
Ammonia/Organic Nitrogen <sup>3</sup>	Monthly	mg/L	< 0.1	ND
Total Chlorine Residual <sup>3,4</sup>	Monthly	mg/L	<0.1	<0.1
Maximum Bacterial Content*** <sup>1,3,4,5</sup>	Weekly	colony forming units (CFU) per milliliter	<10	<1.0
Water Quality <sup>3,4</sup> ratio	Annually	ratio	0.8 – 3.0	1.03
Use Test (Student <i>t</i> ) <sup>3</sup>	Quarterly	N/A	≤ 2.78	≤ 2.78
Inhibitory Residue <sup>4</sup>	Annually	N/A	< 15%	-1.4%
Maximum Silicate, SiO <sub>2</sub> <sup>3,4</sup>	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.

Wendy Hadley  
 Manager of Quality Control

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