



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

For the month of: December 2013 (H13335-H13365)

Listed below are the testing results for the purified water used in the manufacture of products at Hardy Diagnostics. The data was found to meet or exceed the following test specifications which are also outlined in *Standard Methods for the Examination of Water and Wastewater*.⁶

Test	Testing Frequency	Units	In-House Specification (method detection limit)	Testing Data
Minimum Resistivity* ^{1, 5,}	Continuous Monitoring	Megohm* cm	> 16.0	17.83
*pH	Each use	N/A	5.5 – 7.5	5.81
Total Organic Carbon ^{1,5,}	Monthly	ug/L	<500	ND
Heavy Metals* (Single) ^{1, 5,} (Cd, Cr, Cu, Ni, Pb and Zn)	Annually	mg/L	< 0.05	Cd – ND Cr – 0.000096 Cu – 0.000061 Ni – ND Pb – ND Zn – 0.00069
Heavy Metals* (Total) ⁵	Annually	mg/L	< 0.1	ND
Ammonia/Organic Nitrogen ⁵	Monthly	mg/L	< 0.1	ND
Total Chlorine Residual ⁵	Monthly	mg/L	<0.1	ND
Maximum Bacterial Content ^{1,5}	Weekly	colony forming units (CFU) per milliliter	<10	<1
Water Quality ^{5,6} ratio	Annually	ratio	0.8 – 3.0	0.97
Use Test (Student <i>t</i>) ⁵	Quarterly	N/A	≤ 2.78	2.0
Inhibitory Residue	Annually	N/A	< 15%	- 5.3
Maximum Silicate, SiO ₂ ⁵	Annually	mg/L	≤ 0.05	ND

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

*Testing data is given as a monthly average.

References:

1. *Preparation and Testing of Reagent Water in the Clinical Laboratory*, C3-A4. Clinical Laboratory Standards (CLSI), Villanova, PA, 2006.
2. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22-A3. Clinical Laboratory Standards Institute (CLSI – formerly NCCLS), Villanova, PA, 2004.
3. *Standard Methods for the Examination of Water and Wastewater*, 21st ed., editors Andrew D. Eaton, Lenore S. Clesceri, et al. American Public Health Association, Washington, D.C. 2005.
4. *Manual for the Certification of Laboratories Analyzing Drinking Water*, Criteria and Procedures Quality Assurance 5th ed., Environmental Protection Agency (EPA).
5. USP. *USP 35-NF 30, Water for Pharmaceutical Purposes <1231>*. Rockville, MD: US Pharmacopeial Convention; 2012:886-907.

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