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

For the month of: May 2015 (H15121-H15151)

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	16.87
pH*	Each use	N/A	5.5 – 7.5	7.2
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 – 0.00016 Cu – 0.000088 Ni – ND Pb – ND Zn – 0.00064
Heavy Metals (Total) [3,4]	Annually	mg/L	< 0.1	0.0011
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	<0.1
Water Quality [3,4] ratio	Annually	ratio	0.8 – 3.0	1.04
Use Test (Student *t*) [3]	Quarterly	N/A	≤ 2.78	≤ 2.78
Inhibitory Residue [4]	Annually	N/A	< 15%	3.1%
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.

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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