



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

For the month of: May 2014 (H14121-H14151)

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	17.82
pH*	Each use	N/A	5.5 – 7.5	5.86
Total Organic Carbon ^{1,3,5}	Monthly	µg/L	<500	118
Heavy Metals (Single) ^{1,3,4} (Cd, Cr, Cu, Ni, Pb and Zn)	Annually	mg/L	< 0.05	Cd – ND Cr – ND Cu – ND Ni – ND Pb – ND Zn – 0.0011
Heavy Metals (Total) ^{3,4}	Annually	mg/L	< 0.1	0.0011
Ammonia/Organic Nitrogen ³	Monthly	mg/L	< 0.1	**0.42
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
Water Quality ^{3,4} ratio	Annually	ratio	0.8 – 3.0	1.14
Use Test (Student t) ³	Quarterly	N/A	≤ 2.78	2.0
Inhibitory Residue ⁴	Annually	N/A	< 15%	5.3
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.

**This month's water sample was reported to be above the recommended ammonia limit listed above. See results above. A corrective and preventative action plan has been created to correct the issue and prevent its reoccurrence. A review of products related to water testing that were manufactured during this time frame found no evidence to indicate any adverse effects. For further questions, please contact Technical Services.

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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