



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

For the month of: April 2012 12092-12121

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 outlines 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, 3, 4, 5} | Continuous Monitoring | Megohm* cm | > 18.0 | 18.06 |
| *pH | Each use | N/A | 5.5 – 7.5 | 6.90 |
| Total Organic Carbon ^{1, 3, 5} | Monthly | ug/L | <500 | 133 |
| Heavy Metals* (Single) ^{1, 3, 4} (Cd, Cr, Cu, Ni, Pb and Zn) | Annually | mg/L | < 0.05 | Cd – ND Cr – ND Cu – 0.00016 mg/L Ni – 0.00011 mg/L Pb – ND Zn – 0.0013 mg/L |
| 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 |
| Water Quality ^{3, 4} ratio | Annually | ratio | 0.8 – 3.0 | 1.14 |
| Use Test (Student t) ³ | Quarterly | N/A | ≤ 2.78 | ≤ 2.78 |
| Inhibitory Residue ⁴ | Annually | N/A | < 15% | 0% |
| 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. The Official Compendia of Standards. 2008. *USP27-NF22*. United States Pharmacopeial Convention, Rockville, ND.

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