



Purified (Reagent) Water Specification Testing Results (Ohio Facility)
For the month of: November 2015 (H15305-H15334)

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 | 17.68 |
| pH** | Daily | N/A | 5.5 – 7.5 | 7.3 |
| Total Organic Carbon ^{1,3,5} | Monthly | µg/L | <500 | 170 |
| 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 | <0.1 |
| 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 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.

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