

## Purified Water Specification Testing Results (California Facility)

For the month of: July 2014 (14182-14212)

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* <sup>1,3,4,5</sup>                                | Continuous Monitoring | Megohm* cm                                | > 18.0  | 18.10  |
| pH*  | Each use              | N/A                                       | 5.5 – 7.5                                       | 7.06   |
| Total Organic Carbon <sup>1,3,5</sup>                                  | Monthly               | µg/L                                      | <500  | ND   |
| Heavy Metals* (Single) <sup>1,3,4</sup><br>(Cd, Cr, Cu, Ni, Pb and Zn) | Annually              | mg/L                                      | < 0.05  | Cd – ND<br>Cr – ND<br>Cu – ND<br>Ni – ND<br>Pb – ND<br>Zn – ND |
| Heavy Metals* (Total) <sup>3,4</sup>                                   | Annually              | mg/L                                      | < 0.1   | ND   |
| Ammonia/Organic Nitrogen <sup>3</sup>                                  | Monthly               | mg/L                                      | < 0.1   | ND   |
| Total Chlorine Residual <sup>3,4</sup>                                 | Monthly               | mg/L                                      | <0.1  | ND   |
| Maximum Bacterial Content <sup>1,3,4,5</sup>                           | Weekly                | colony forming units (CFU) per milliliter | <10   | <1   |
| Water Quality <sup>3,4</sup> ratio                                     | Annually              | ratio                                     | 0.8 – 3.0                                       | 1.12   |
| Use Test (Student t) <sup>3</sup>                                      | Quarterly             | N/A                                       | ≤ 2.78  | 2.0  |
| Inhibitory Residue <sup>4</sup>  | Annually              | N/A                                       | < 15%   | - 4%   |
| Maximum Silicate, SiO <sub>2</sub> <sup>3,4</sup>                      | 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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