

Reagent Water Specification Testing Results

For the month of: February 2012 12032-12060

Listed below are the testing results for the reagent 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 outlined in *Standard Methods for the Examination of Water and Wastewater*⁴.

Test	Testing Frequency	In-House Specification (method detection limit)	Testing Data
*Minimum Resistivity, (Continuous monitoring)	Daily	> 18 Megohm	18.13
*pH	Each Use	5.5 – 7.5	7.17
Total Organic Carbon	Monthly	< 1.0 mg/L	ND
Heavy Metals (Single) (Cd, Cr, Cu, Ni, Pb, Zn)	Annually	< 0.05 mg/L	Cd – 0.000023 mg/L Cr – 0.000089 mg/L Cu – 0.000069 mg/L Ni – ND Pb – ND Zn – 0.00074 mg/L
Heavy Metals (Total)	Annually	< 0.1 mg/L	0.00095 mg/L
Ammonia/Organic Nitrogen (TKN)	Monthly	< 0.1 mg/L	ND
Total Chlorine Residual	Monthly	< Detection Limit (Hardy DL = 0.1 mg/L)	ND
*Heterotrophic Plate Count	Weekly	< 500 CFU/ml	<1
Water Quality	Annually	0.8 – 3.0 ratio	1.0
Use Test	Quarterly	Student's $t \le 2.78$	2.0
Inhibitory Residue	Annually	< 15%	0%
Maximum Silicate, SiO ₂	Annually	≤ 0.1 mg/L	ND

ND = Not Detected at or above the method detection limit.

References:

- 1. Preparation and Testing of Reagent Water in the Clinical Laboratory, C3-A3. Clinical Laboratory Standards Institute (CLSI formerly NCCLS), Villanova, PA, 1997.
- 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, 19th ed., editor Lenore S. Clesceri, et al. American Public Health Association, Washington, D.C. 1995.
- 4. Standard Methods for the Examination of Water and Wastewater, 20th ed., editor Lenore S. Clesceri, et al. American Public Health Association, Washington, D.C. 1998.
- 5. Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures Quality Assurance 5th ed., Environmental Protection Agency (EPA).

Wendy Hadley

Quality Control Manager

Wendy Hadley

Hardy Diagnostics 1430 W. McCoy Lane

Santa Maria, CA 93455 (800) 266-2222 FAX (805) 346-2760 www.hardydiagnostics.com

^{*}Testing data is given as a monthly average.