



Reagent Water Specification Testing Results

For the month of: September 2010 (Lot#10244 – 10273)

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	18.23
*pH	Each Use	5.5 – 7.5	6.83
Total Organic Carbon	Monthly	< 1.0 mg/L	0.787 mg/L
Heavy Metals (Single) (Cd, Cr, Cu, Ni, Pb, Zn)	Annually	< 0.05 mg/L	Cd – ND Cr – ND Cu – ND mg/L Ni – ND mg/L Pb – ND Zn – 0.0011 mg/L
Heavy Metals (Total)	Annually	< 0.1 mg/L	0.0011 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	0
Water Quality	Annually	0.8 – 3.0 ratio	1.01
Use Test	Quarterly	Student's $t \leq 2.78$	2.0
Inhibitory Residue	Annually	< 15%	0%
Maximum Silicate, SiO ₂	Annually	≤ 0.1 mg/L	0.056 mg/L

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-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).

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