

November 2, 2009

RE: CLIA WAIVER CERTIFICATION FOR CLARITY UROCHECK 120 URINE ANALYZER

Dear Customer,

We hereby certify that *Clarity* Urocheck 120 Urine analyzer is FDA cleared and CLIA Waived.

The FDA document number for the CLIA waiver is **k070929** dated October 28, 2009.

Only use *Clarity* Urinalysis Reagent Strips on the *Clarity* Urocheck 120 Urine Analyzer for proper function and accurate results. Users should read the complete test procedure before performing a test using this analyzer.

Only laboratories with a Certificate of CLIA Waiver may use the *Clarity* Urocheck 120 Urine Analyzer in a waived setting. Failure to adhere to the instructions for use and for performing QC testing is considered off-label use. Off-label use is categorized as high complexity and subject to all CLIA regulations.

If you have any further questions or need any further documentation, please feel free to contact me directly.

Sincerely,



Ashish Parikh

Chief Technical Officer

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