

K 964409

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510 (k) Summary of Safety and Effectiveness

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS OF THE HCL-200 CLINICAL CHEMISTRY ANALYZER:

Submitted by:

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Identification:

- Trade Name: HCL - 200 Biochemistry Analyzer.
- Common or usual name: Clinical Chemistry Analyzer
- Classification name: Micro Chemistry Analyzer for Clinical Use.

Description:

The HCL-200 is an automated discrete random access in vitro diagnostic multichannel chemistry analyzer. It is composed of two modules:

- The liquid handling system includes compartments of reagents and samples as well as the pipetting unit.
- The reaction module includes the cuvette turntable to which samples and reagents are transferred. A photometer to monitor reaction response is also contained in this unit.

Then analyzer is linked to a PC compatible computer which loads software into each of the two modules.

Intended Use:

The HCL - 200 is intended for use as an in vitro diagnostic multichannel chemistry analyzer.

Technological Characteristics Compared to the Predicate Device

The functions of the HCL-200 and the COBAS MIRA [510 (k) K851172] are fundamentally the same. The basic physical principles for measurement of radiant energy, absorbed or transmitted, under controlled conditions are the same. Both instruments are automated interference filter photometers capable of measuring monochromatic light with wavelengths between 340 and 700 nm.

Substantial Equivalence and Summary Performance Data:

NCCLS evaluation protocols were used to demonstrate substantially equivalent performance between the HCL-200 and the predicate device. NCCLS Documents used in the evaluation of HCL-200 and the comparison to the Roche COBAS MIRA are listed below:

Table 3 NCCLS Protocols Used in Evaluation/ Comparison	
NCCLS Document Number	Document Title
EP 10 - T2 Vol. 13 No, 10	Preliminary Evaluation of Quantitative Clinical Laboratory Methods, Second Edition
EP6-P Vol. 6 No. 18	Evaluation of the Linearity of Quantitative Analytical Methods
EP5 - T2 Vol. 12, No.4	Evaluation of Precision Performance of Clinical Chemistry Devices, Second Edition
EP9 - T Vol. 13 No. 4	Method Comparison and Bias Estimation Using Patient Samples.

Method protocols (applications) for OEM supplied reagents listed below were developed on the instrument after a two week device familiarization period as described in the NCCLS Documents. Preliminary evaluations using NCCLS EP 10 - T2 were run on each reagent in order to optimize application parameters.

Table 4 OEM Supplied Reagents			
REAGENT NAME	510k Number	REAGENT NAME	510k Number
Albumin	K831585	CRP	K902593
ALT (GPT)	K820525	GGT	K905085
Amylase	K861718	Glucose, Hexokinase UV	K801765
AST (GOT)	K820270	LDH-L	K822312
Bilirubin, Total	K841892	Phosphorus	K870776
BUN, Rate	K812417	Total Protein	K841466
CK NAD, Imidazole	K905084/A	Triglycerides GPO	K842029/A
Creatinine, (Jaffe)	K840872	Uric Acid	K812641

A summary of pertinent statistical results are presented in the table on the following two (2) pages:

Table 5 Performance Data Summary

REAGENT NAME	LINEARITY	SIMPLE PRECISION	COMPLEX PRECISION	COMPARISON TO PREDICATE (COBAS MIRA)
Albumin	Number [N]: 5 Linear Range: 2 TO 8.5 g/dL	Number [N]: 20 Normal: CV: 1.8% Abnormal CV: 1.7%	Number [N]: 80 Normal: CV: 8% Abnormal CV: 6.4%	Number [N]: 100 Slope [m]: 1.000 Intercept [b]: -0.03 Correlation Coeff. [r]: 0.987
ALT (GPT)	Number [N]: 7 Linear Range: 0 to 650 U/L	Number [N]: 20 Normal: CV: 3% Abnormal CV: 1.5%	Number [N]: 80 Normal: CV: 4.6% Abnormal CV: 2.1%	Number [N]: 104 Slope [m]: 1.08 Intercept [b]: 0.6 Correlation Coeff. [r]: 0.998
Amylase	Number [N]: 9 Linear Range: 0 to 2500 U/L	Number [N]: 20 Normal: CV: 4.6% Abnormal CV: 1.7%	Number [N]: 80 Normal: CV: 5.0% Abnormal CV: 3.5%	Number [N]: 101 Slope [m]: 1.09 Intercept [b]: -2.8 Correlation Coeff. [r]: 0.999
AST (GOT)	Number [N]: 6 Linear Range: 0 to 650 U/L	Number [N]: 20 Normal: CV: 3.5% Abnormal CV: 2.6%	Number [N]: 80 Normal: CV: 6.1% Abnormal CV: 4.6%	Number [N]: 100 Slope [m]: 1.05 Intercept [b]: -0.6 Correlation Coeff. [r]: 0.997
Bilirubin, Total	Number [N]: 6 Linear Range: 0 to 20 mg/dL	Number [N]: 20 Normal: CV: 2.8% Abnormal CV: 1.5%	Number [N]: 80 Normal: CV: 7.3% Abnormal CV: 9.0%	Number [N]: 100 Slope [m]: 0.902 Intercept [b]: 0.11 Correlation Coeff. [r]: 0.993
BUN, Rate	Number [N]: 5 Linear Range: 0 to 125mg/dL	Number [N]: 20 Normal: CV: 4.1% Abnormal CV: 1.9%	Number [N]: 80 Normal: CV: 5.8% Abnormal CV: 5.2%	Number [N]: 100 Slope [m]: 0.948 Intercept [b]: 1.1 Correlation Coeff. [r]: 0.996
CK NAD, Imidazole	Number [N]: 8 Linear Range: 0 to 2100 U/L	Number [N]: 20 Normal: CV: 2.3% Abnormal CV: 2.3%	Number [N]: 80 Normal: CV: 4.6% Abnormal CV: 2.1%	Number [N]: 100 Slope [m]: 1.034 Intercept [b]: 5.6 Correlation Coeff. [r]: 0.999
Creatinine, (Jaffe)	Number [N]: 5 Linear Range: 0 to 12.5 mg/dL	Number [N]: 20 Normal: CV: 2.45% Abnormal CV: 1.9%	Number [N]: 80 Normal: CV: 7.2% Abnormal CV: 3.1%	Number [N]: 103 Slope [m]: 0.994 Intercept [b]: 0.045 Correlation Coeff. [r]: 0.997

Table 5 Performance Data Summary, continued

REAGENT NAME	LINEARITY	SIMPLE PRECISION	COMPLEX PRECISION	COMPARISON TO PREDICATE (COBAS MIRA)
CRP	Number [N]: Linear Range: not applicable. Limits of Standard Curve: 5 to 129 mg/dL	Number [N]: 20 Normal: CV: 6.3% Abnormal CV: 1.9%	Number [N]: 80 Normal: CV: 6.7% Abnormal CV: 2.6%	Number [N]: 100 Slope [m]: Intercept [b]: Correlation Coeff. [r]: 0.992
GGT	Number [N]: 8 Linear Range: 0 to 1000 U/L	Number [N]: 20 Normal: CV: 2.9% Abnormal CV: 1.3%	Number [N]: 80 Normal: CV: 5.9% Abnormal CV: 2.2%	Number [N]: 100 Slope [m]: 1.07 Intercept [b]: -0.9 Correlation Coeff. [r]: 0.999
Glucose, Hexokinase UV	Number [N]: 5 Linear Range: 0 to 600 mg/dL	Number [N]: 20 Normal: CV: 2.6% Abnormal CV: 2.3%	Number [N]: 80 Normal: CV: 1.0% Abnormal CV: 2.9%	Number [N]: 400 Slope [m]: 0.998 Intercept [b]: 7.5 Correlation Coeff. [r]: 0.992
LDH-L	Number [N]: 9 Linear Range: 0 to 1000 U/L	Number [N]: 20 Normal: CV: 2.1% Abnormal CV: 0.5%	Number [N]: 80 Normal: CV: 2.8% Abnormal CV: 1.9%	Number [N]: 100 Slope [m]: 1.06 Intercept [b]: 16.2 Correlation Coeff. [r]: 0.992
Phosphorus	Number [N]: 6 Linear Range: 0 to 15.0 mg/ dL	Number [N]: 20 Normal: CV: 2.9% Abnormal CV: 1.2%	Number [N]: 80 Normal: CV: 5.5% Abnormal CV: 3.1%	Number [N]: 111 Slope [m]: 1.06 Intercept [b]: 0.0 Correlation Coeff. [r]: 0.985
Total Protein	Number [N]: 5 Linear Range: 0 to 12 g/dL	Number [N]: 20 Normal: CV: 1.6% Abnormal CV: 0.9%	Number [N]: 80 Normal: CV: 2.4% Abnormal CV: 1.9%	Number [N]: 102 Slope [m]: 1.05 Intercept [b]: -0.09 Correlation Coeff. [r]: 0.983
Triglycerides GPO	Number [N]: 5 Linear Range: 0 to 1000 mg/dL	Number [N]: 20 Normal: CV: 2.8% Abnormal CV: 1.6%	Number [N]: 80 Normal: CV: 4.2% Abnormal CV: 3.3%	Number [N]: 102 Slope [m]: 1.025 Intercept [b]: -2.5 Correlation Coeff. [r]: 0.994
Uric Acid	Number [N]: 5 Linear Range: 0 to 20 mg/dL	Number [N]: 20 Normal: CV: 1.7% Abnormal CV: 1.8%	Number [N]: 80 Normal: CV: 4.2% Abnormal CV: 4.8%	Number [N]: 100 Slope [m]: 1.02 Intercept [b]: -0.25 Correlation Coeff. [r]: 0.987

Claim of Substantial Equivalence to Predicate Device

The safety and effectiveness of the HCL-200 Clinical Chemistry Analyzer is evidenced by:

1. Its equivalent performance to the predicate device, the Roche COBAS MIRA, as summarized in table 5 above and,
2. the fact that the two devices are virtually identical in terms of their use of basic principles of radiant energy measurement, automated liquid handling and data management capabilities.