

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k053612

B. Purpose for Submission:

New Assay

C. Analyte:

acid phosphatase

D. Type of Test:

automated spectrophotometric assay

E. Applicant:

Beckman Coulter, Inc.

F. Proprietary and Established Names:

Dri-STAT® ACP Reagent

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1020, Acid Phosphatase Test System.
2. Classification:
Class II
3. Product Code:
CKB
4. Panel:
75 Chemistry

H. Intended Use:

1. Intended use:
Dri-Stat Reagent ACP is intended for use in the in vitro diagnostic determination of total acid phosphatase and non-prostatic acid phosphatase in human serum as a User Defined Reagent (UDR) application on SYNCHRON Systems.
2. Indications for use:
See intended use.
3. Special condition for use statement(s):
For prescription use.

4. Special instrument requirement(s):
For use on Synchron Systems CX and LX.

I. Device Description:

The test consists of the reagents α -naphthylphosphate, FAST RED TR, L-tartrate and acetate buffer.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Dri-STAT® Reagent ACP on Cobas Fara
2. Predicate K number(s):
k821674
3. Comparison with predicate:
The devices have the same intended use and methodology. The instrument applications are different.

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP5-A - Evaluation of Precision Performance of Clinical Chemistry Devices
CLSI EP-17A - Protocols for Determination of Limits of Detection and Limits of Quantitation

L. Test Principle:

The reagents include α -naphthylphosphate, which is converted to α -naphthol in the presence of ACP; and FAST RED TR, which reacts with α -naphthol to produce a chromogen. The increase in absorbance at 405 nm is proportional to the concentration of ACP in the sample. The test is run in the absence and presence of tartrate. The difference between the two values for each sample is attributed to the prostatic isoenzyme.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
Evaluations were performed on the Synchron CX and LX.

a. Precision/Reproducibility:

Precision was evaluated at the manufacturer's site using the manufacturer's serum control material as well as serum pools spiked with (potato) acid phosphatase. Calculations, based on 2 runs/day, with 2 replicates per run, over 20 consecutive days, were performed according to CLSI (NCCLS) EP-5A.

Data presented in the 510(k) was obtained from a single instrument. The manufacturer reports that results from 4 instruments were similar. Results in the 510(k) met the following manufacturer's acceptance criteria:

Within-run: SD < 1.0U/L (below 33.3U/L) or < 3.0% CV (above 33.3 U/L)
 Total: SD < 1.5 U/L (below 33.3 U/L) or < 4.5% CV (above 33.3 U/L)

b. Linearity/assay reportable range:

Evaluations were based on multiple inter-dilutions of spiked patient specimens with zero-level serum samples. Seven dilution levels across the range of the assay were prepared and each level was evaluated in triplicate. Linearity of non-prostatic acid phosphatase (NPAP) and total acid phosphatase (TACP) were measured separately. Target values were defined based on the middle dilution levels and the dilution factors. The assay range is 2.0-38.0 ug/ml. Average recovery (of triplicates at each level), relative to the target value, was near 100% for TACP and within +/- 5% of 100% for NPAP.

c. Traceability (controls, calibrators, or method):

Controls were cleared under k82264 and were not reviewed in this 510(k). The assay is a non-calibrated enzymatic assay.

The following are used to evaluate comparison across lots:

- i. Each new lot of reagent is tested for recoveries using 3 levels of control materials, and a previous lot of reagent is tested at the same time as a reference. The manufacturer's acceptance criteria for new lots is to recover within insert range of the Level 1 control, within ± 2 U/L of the insert mean for Level 2 and within ± 3 U/L of the insert mean for Level 3 control values.
- ii. Acceptance criteria for the methods comparison studies are slopes of 1.0 ± 0.15 , intercepts of within ± 2 S.D or ± 2 U/L and an R of ≥ 0.990 .

d. Detection limit:

The evaluation of limit of detection was based on the CLSI Protocol EP-17A. A saline blank and a low level sample, were evaluated. Results are shown below. Additional sensitivity testing, performed using human albumin in saline as a blank yielded similar results.

Results (U/L)				
	Blank sample		Low concentration sample	
	Total acid phosphatase	Non-prostatic	Total	Non-prostatic
Average	0.4	0.4	1.7	1.8
Standard deviation	0.3	0.2	0.2	0.3
Min	0.0	0.0	1.4	1.1
Max	1.0	0.9	2.1	2.4

e. Analytical specificity:

Endogenous compounds were spiked into pooled patient serum samples containing three levels of ACP. Samples at each level were spiked with interferent to concentrations as high as 30 mg/dL bilirubin, 500 mg/dL Intralipid, and 500 mg/dL hemoglobin and results were compared to those of control samples without interferent. Recovery relative to the control were within ± 2 U/L, or 6% of expected results for samples containing intralipid and bilirubin. Reduced recovery was observed in some samples containing hemoglobin near 125 mg/dL, though all results were within ± 4 U/L.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device

Samples were evaluated on the Cobas Fara (predicate) and on the Synchron CX and LX Systems. Patient samples were evaluated and also supplemented with spiked samples, especially at the high range. Results of analysis by Deming regression are shown below.

Analyte	Instruments	Slope (CI)	Intercept (CI)	Data range (U/L)	R	Std err (U/L)	N
TACP	LX (X) vs. COBAS FARA (Y)	1.09 (± 0.03)	0.15 (± 0.39)	X=2-34 Y=2-37	0.994	0.92	94
NPAP	LX vs. COBAS FARA	1.07 (± 0.07)	-0.20 (± 1.20)	X=2-34 Y=2-36	0.980	1.27	47
TACP	CX vs. COBAS FARA	1.08 (± 0.02)	0.46 (± 0.28)	X=2-34 Y=2-37	0.997	0.65	94
NPAP	CX vs. COBAS FARA	1.05 (± 0.03)	-0.17 (± 0.57)	X=2-34 Y=2-36	0.995	0.67	47

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical sensitivity:

Not applicable. (Not typically reviewed for this type of test.)

b. Clinical specificity:

Not applicable. (Not typically reviewed for this type of test.)

4. Clinical cut-off: See expected values.

5. Expected values/Reference range:

The following expected range in the product's Chemistry Information Sheet is cited from the literature.

	Total	Prostatic
Serum (Male)	2.5 - 11.7 U/L	0.2 - 3.5 U/L
Serum (Female)	0.3 - 9.2 U/L	0 - 0.8 U/L

In addition, a small verification study (n=20 males, 20 females) using the Synchron System was performed; all results fell within the expected range cited in the literature.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports substantial equivalence decision.