

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

A. 510(k) Number:

k033297

B. Analyte:

Human chorionic gonadotropin

C. Type of Test:

Qualitative

D. Applicant:

ZBX Corporation

E. Proprietary and Established Names:

ZAP™ hCG Test

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1155
2. Classification:
Class II
3. Product Code:
JHI
4. Panel:
75

G. Intended Use:

1. Intended use(s):
The ZAP™ hCG Test is an immunoassay used for the qualitative detection of human chorionic gonadotropin in human whole blood (capillary and heparinized venous), plasma, or serum and is indicated as an aid for health care professionals in the diagnosis of early pregnancy.
2. Indication(s) for use:
The ZAP™ hCG Test is an immunoassay used for the qualitative detection of human chorionic gonadotropin in human whole blood (capillary and heparinized venous), plasma, or serum and is indicated as an aid for health care professionals in the diagnosis of early pregnancy.
3. Special condition for use statement(s):
Prescription use; Point of care use.
4. Special instrument Requirements:
Not applicable

H. Device Description:

The ZAP™ hCG Test is composed of a sample application region; receiving channel that fills with sample before it flows to the plasma separator membrane; plasma separator membrane that traps red blood cells and contains monoclonal mouse anti-hCG antibodies conjugated to colloidal gold (detector antibodies); and an analytical nitrocellulose membrane containing polyclonal goat anti-hCG antibodies immobilized in the test band region and rabbit anti-mouse antibodies immobilized in the control band region. The tests strips are packaged in individually sealed pouches.

I. Substantial Equivalence Information:

1. Predicate device name(s):
ICON® II HCG ImmunoConcentration Assay
2. Predicate K number(s):
k860542
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	For health care professional use for the early detection of pregnancy	For health care professional use for the early detection of pregnancy
Differences		
Item	Device	Predicate
Intended Use/Samples	Qualitative detection of hCG in whole blood, plasma or serum	Qualitative detection of hCG in urine; semi-quantitative detection of hCG in serum
Detector Antibody	Monoclonal antibody to hCG linked to colloidal gold	Monoclonal antibody to hCG linked to alkaline phosphatase
Test Procedure	One-step, no reagents required	Multi-step, multiple reagent additions
Sensitivity	10 mIU/mL (all samples)	10 mIU/mL (serum) 20 mIU/mL (urine)

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

None Referenced

K. Test Principle:

The ZAP™ hCG Test is an immunochromatographic assay.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Three samples of normal human whole blood were spiked with hCG to attain concentrations less than or above the cut-off value of 10 mIU/mL. Three different hospitals were each provided with five (5) replicates of each sample (15 blind labeled tubes in total). The sponsor also analyzed the fifteen samples. The results showed complete agreement between sites for each sample tested.

b. *Linearity/assay reportable range:*

Not applicable

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

The test was calibrated with the Abbott ARCHITECT Total β -hCG assay, which is calibrated with material referenced to the WHO 3rd International Standard.

d. *Detection limit:*

The test band was designed to be visible when a specimen containing an hCG concentration of approximately 10 mIU/mL is analyzed by the test.

Three hCG positive patient serum pools were prepared to have concentrations near 20, 10, and 5 mIU/mL hCG. Twenty (20) replicates of each pool for a total of sixty (60) samples were tested with the ZAP™ hCG Test. The ZAP™ hCG Test correctly identified the forty (40) positive samples and the twenty (20) negative samples.

e. *Analytical specificity:*

The following related hormones were added to human negative serum: thyroid stimulating hormone (1000 μ IU/mL hTSH), luteinizing hormone (500 mIU/mL hLH), and follicle stimulating hormone (1000 mIU/mL hFSH). Samples were tested on the ZAP™ hCG Test in duplicate. The results were all negative for the samples containing hTSH, hLH, and hFSH at the specified concentrations.

Interfering substances (human albumin, unconjugated bilirubin, free hemoglobin, and triglycerides) were added to human negative serum and human positive hCG sera (10 mIU/mL and 60 mIU/mL). Samples were tested on the ZAP™ hCG Test in duplicate. The negative and positive hCG sera gave the expected results at 14 g/dL, 15 mg/dL, 250 mg/dL, and 2000 mg/dL, respectively.

f. *Assay cut-off:*

See Detection limit above.

2. Comparison studies:

a. *Method comparison with predicate device:*

A comparison study between the ZAP™ hCG Test and the predicate device was performed using one hundred and sixteen (116) female serum samples. Samples were quantitated with another commercially available assay, and fifty-nine (59) samples ranged between 10 and

200 mIU/mL. Fifty-seven (57) samples were below the 10 mIU/mL cut-off.

For the hCG positive samples, there was 100% agreement between the two assays. There were four discrepant samples in which the other test gave positive results and the ZAP™ hCG Test gave negative results. The discrepant samples had hCG concentrations in the range of 2-6 mIU/mL and were correctly reported as negative by the ZAP™ hCG Test based on the test's cut-off. There was 100% agreement between the two assays for the remaining fifty-three (53) samples.

b. Matrix comparison:

A correlation between whole blood and plasma was performed. Heparinized whole blood from a non-pregnant female was spiked with hCG to attain samples with concentrations of <1.2, 4, 9, and 19 mIU/mL hCG when plasma recovered from the spiked blood was quantitated. Both blood and corresponding plasma samples for a total of four (4) sets of samples were tested with the ZAP™ hCG Test. Each set was tested five (5) times.

The results were as follows: The agreement between whole blood and plasma was 100% for hCG values greater than or equal to 9 mIU/mL. Two tests gave a weak positive signal at 4 mIU/mL hCG for whole blood.

3. Clinical studies:

a. Clinical sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a and b are not applicable):

Clinical personnel obtained forty (40) capillary blood samples from female patients and tested the samples using the ZAP™ hCG Test. The operators were blinded to the diagnoses of the patients. Diagnoses were based on patient history and the results of either ultrasound or quantitative testing of serum.

There were no discrepancies between the ZAP™ hCG Test results and patient diagnosis. The ZAP™ hCG Test positively identified twenty-six (26) of the forty (40) patients that were pregnant. Of the twenty-six (26) pregnant patients, eight (8) were tested within -1 day and +9 days of the missed menstrual period. The other eighteen (18) patients were tested between two weeks to seventeen weeks after the missed menstrual period.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values were established using literature.

M. Conclusion:

The ZAP™ hCG Test is similar to the predicate device in that both tests detect hCG as an aid in early detection of pregnancy by health care professionals. The two tests differ in sample matrices that can be used; however, this does not raise new issues of safety or effectiveness. There are other commercially available assays that process whole blood (via a plasma separating mechanism) to determine the presence of hCG.

The ZAP™ hCG Test is similar to the predicate device in that both tests are immunoassays, although the new test uses monoclonal antibodies conjugated to colloidal gold as opposed to the predicate which uses monoclonal antibodies conjugated to alkaline phosphatase. Both reagents are well-established in the scientific community. Additionally, the plasma separating mechanism in the new device has been reviewed in other commercially available assays and does not raise any new issues of safety or effectiveness.

In addition to the descriptive characteristics, the various performance data provided demonstrated that the ZAP™ hCG Test was similar to the predicate device and other commercially available assays. Therefore, a substantial equivalence determination is recommended for the ZAP™ hCG Test.