510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K201049

B Applicant

Baebies, Inc.

C Proprietary and Established Names

FINDER G6PD Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JBF	Class II	21 CFR 864.7360 - Erythrocytic Glucose-6-Phosphate Dehydrogenase Assay	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

G6PD enzymatic activity

C Type of Test:

Semi-quantitative

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The FINDER G6PD test is intended for semi-quantitative measurement of glucose-6-phosphate dehydrogenase in venous whole blood specimens collected in lithium heparin tubes, for the identification of G6PD deficient samples. The FINDER G6PD test is intended to be used with the FINDER Instrument in point of care or clinical laboratory settings.

Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

C Special Instrument Requirements:

FINDER Instrument

IV Device/System Characteristics:

A Device Description:

The FINDER G6PD test system consists of the following main components:

- FINDER Cartridge – The FINDER Cartridge uses electrowetting-based digital microfluidics to integrate and automate all the sample and reagent handling steps required to perform the G6PD test. The cartridge is single-use and contains the following reagents necessary to perform the test:

Reagent Name	Component
FINDER G6PD Reagent 1	NADP+ 7.4µg, Maleimide 1.9µg, Buffers, stabilizers
FINDER G6PD Reagent 2	G6P 0.56µg Buffers, stabilizers
Other Inactive ingredients	Water with surfactants, Silicone Oil, agglutinating agent

- FINDER Instrument – The FINDER Instrument contains all the hardware and software required to operate the FINDER Cartridge. The instrument provides electrowetting control, thermal control, and detection capability, required to perform the G6PD test. The instrument also provides a touch-screen user interface and software necessary to perform the test and report results.

The FINDER G6PD test system also includes a 50 µL fixed-volume micropipette used to transfer specimens from the specimen collection device to the FINDER Cartridge for testing, as well as an optional thermal printer that is connected to the instrument via USB.

B Principle of Operation:

G6PD activity is measured from a whole blood sample input. Red blood cells are lysed osmotically in the cartridge by combining whole blood with water. The lysed blood cells are then incubated with β-nicotinamide adenine dinucleotide phosphate (NADP) and glucose-6-phosphate (G6P), resulting in the production of NADPH. Kinetic fluorescence measurements are used to quantify the rate of NADPH production, which is proportional to G6PD enzymatic activity. The reaction occurs in the presence of maleimide, which is used to improve the specificity of the test by inhibiting the production of NADPH from 6-phosphogluconate dehydrogenase. Hemoglobin present in the lysed sample is measured by absorbance and used to normalize G6PD enzymatic activity, resulting in a final reported unit of U/gHb.

The FINDER G6PD test reports the hemoglobin normalized G6PD activity in U/gHb and a percentage of the site-specific Adjusted Male Median (%AMM). The site-specific AMM is calculated using a minimum of 36 normal male samples and can be set by the user.

Instrument Description Information:

1. Instrument Name:
   FINDER Instrument

2. Specimen Identification:
   Specimen identification is performed by use of a barcode reader in the FINDER Instrument.

3. Specimen Sampling and Handling:
   Venous whole blood samples are collected into lithium-heparin devices. Blood collection devices should be used in accordance with the manufacturer's labeling, including adhering to specific fill volume requirements. To perform a test on the FINDER device, 50 µL of lithium-heparin whole blood sample is required.

4. Calibration:
   Each lot of FINDER cartridge is factory calibrated by the manufacture and the calibration data for each test is included within the 2D barcode label that is placed on the Cartridge. This barcode is scanned at the beginning of each test.

5. Quality Control:
   Performance of the FINDER system can be verified by analyzing commercially available off-the-shelf hemolysate quality control materials. The quality control material should be run at the start of each day.

V Substantial Equivalence Information:

A Predicate Device Name(s):
G6PDH, Glucose-6-phoshate Dehydrogenase

B Predicate 510(k) Number(s):
K024006

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201049	K024006
Device Trade Name	FINDER G6PD test	G6PDH, Glucose-6-phoshate Dehydrogenase
General Device Characteristic Similarities		
Regulation	21 CFR 864.7360	Same
Product Code	JBF	JBF
Intended Use/Indications For Use	The FINDER G6PD test is intended for semi-quantitative measurement of glucose-6-phosphate dehydrogenase in venous whole blood specimens collected in lithium heparin tubes, for the-identification of G6PD deficient samples. The FINDER G6PD test is intended to be used with the FINDER Instrument in point of care or clinical laboratory settings.	For the quantitative determination of glucose-6-phosphate dehydrogenase (G6PD) in blood at 340 nm. For in vitro diagnostic use only.
Analytes	G6PD	Same
Specimen	Whole blood	Same
Controls	Hemolysate	Same
Calibration Traceability	Absorptivity of NADPH	Same
Component Reagent matrices	G6P, Buffer, NADP and Maleimide	Same
Sensitivity (Limit of Detection)	0.4 U/gHb	0.4 U/gHb
General Device Characteristic Differences		
Analyzer	FINDER Instrument	Cobas Mira
Reagent Format	Dry test-specific reagents and liquid diluent and filler fluid; reconstitution performed by instrument	Dry and liquid, ready to use reagents; manual reconstitution
Method	NADPH kinetic fluorometric method	NADPH kinetic spectrophotometric

		method
Anticoagulant	Li-Heparin	EDTA, Heparin, ACD
Detection of analyte, Measurand	Fluorometric, semi-quantitative 370 nm Excitation/460 nm Emission	Spectrophotometric, quantitative at 340 nm
Linear Range	0.8 to 19.7 U/gHb	2.78 to 20.69 U/gHb
Limit of Blank	0.2 U/gHb	Not specified
Limit of Quantitation	1.1 U/gHb	Not specified

VI Standards/Guidance Documents Referenced:

- ISO 13485:2016, Medical Devices – Quality Management Systems
- ISO 15223-1:2016, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
- ISO 14971:2007, Application of Risk Management to Medical Devices
- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
- CLSI EP06, Evaluation of the Linearity of Quantitative Measurement Procedures; 2nd Edition
- CLSI EP07, Interference Testing in Clinical Chemistry; Third Edition
- CLSI EP17-A2 , Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
- IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
- IEC 61010-1:2010/AMD1:2016/COR1:2019, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
- IEC 61010-2-010:2014, Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-010: Particular requirements for laboratory equipment for the heating of materials
- IEC 61010-2-010:2019, Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-010: Particular requirements for laboratory equipment for the heating of materials
- IEC 61010-2-101:2015, Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 61010-2-101:2018, Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 60601-1-2:2007, Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility
- EN 61326-1:2013, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements

- EN 61326-2-6:2013, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
- EN 61000-3-2:2014, Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
- EN 61000-3-3:2013, Electromagnetic compatibility (EMC) – Part 3-3: Limits –Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Precision studies were designed in accordance with CLSI EP05-A3.
   Single-site precision study was performed at one internal site over a period of 21 non-consecutive days with two runs per day and two replicates per run. Three hemolysate quality control samples were used to create three concentrations of G6PD (low = 1.4 U/gHb, medium = 7.0 U/gHb, high = 17.4 U/gHb). Samples were tested by two qualified operators on a total of three FINDER instruments. Three lots of FINDER G6PD Test Cartridges were used in the study.

Summary of Single-Site Precision Study

Sample	N	Mean (U/gHb)	Repeatability (%CV)	Between-run (%CV)	Between-Day (%CV)	Between-Operator (%CV)	Between-Lot (%CV)	Between-Instrument (%CV)	Within-Laboratory Precision (%CV)
LOW	84	1.4	4.1%	3.2%	0.7%	0.0%	0.0%	3.8%	6.5%
INTER	84	7.0	3.6%	2.2%	1.1%	0.0%	1.8%	2.4%	5.3%
HIGH	84	17.4	2.4%	2.6%	0.0%	0.0%	0.0%	3.9%	5.2%

The reproducibility study was conducted at three separate laboratories using fresh whole blood samples that were prepared each of five days by appropriate dilution to obtain three target G6PD levels (low ≤ 2.0 U/gHb, medium = 3.0–5.0 U/gHb, and high ≥ 8.0 U/gHb). Each day, aliquots at the three sample levels were delivered to each testing lab, where they were subdivided into eight samples that were evaluated on two instruments running by two operators, with two replicates each. A total of 15 samples (three G6PD levels, prepared on each of five days) were evaluated, and each sample was measured by the FINDER Instrument 24 times (across three sites, two instruments, two operators per site, two replicates), resulting in a total of 360 measurements for analysis.

Summary of Reproducibility Study

Sample	N	Mean (U/gHb)	Repeatability (%CV)	Between-Site (%CV)	Between-Instrument (%CV)	Between - Operator (%CV)	Reproducibility (%CV)
LOW	120	1.1	5.9%	0.0%	0.9%	0.0%	6.0%
INTER	120	3.5	3.4%	0.7%	2.5%	1.0%	4.4%
HIGH	120	11.2	6.6%	0.5%	0.6%	2.2%	7.0%

2. Linearity:
Linearity was evaluated in accordance with CLSI EP06-A. The linearity test for FINDER G6PD test was conducted in two separated studies and linearity range was determined to be 0.8 to 19.7 U/gHb.

The first linearity study used contrived samples of recombinant G6PD enzyme spiked into whole blood to achieve activity levels that cover the intended linear range of the product. Nine samples were generated with increasing levels of G6PD activity from 2.0 to 19.7 U/gHb. Each level was tested in eight replicates using a single lot of the FINDER G6PD Test Cartridge by three operators on six FINDER instruments.

The second study used whole blood from a normal donor and a G6PD-deficient donor. The native linearity study was performed to ensure that linearity demonstrated in the contrived study is not an artifact associated with usage of recombinant G6PD. Nine whole blood samples were prepared with increasing levels of G6PD activity from 0.8 to 13.9 U/gHb. Each level was tested in eight replicates using a single lot FINDER G6PD Test Cartridge by two operators on six FINDER instruments.

3. Analytical Specificity/Interference:
Interference was evaluated in accordance with CLSI EP07.
One lot of FINDER G6PD Test Cartridges was used at the internal site. Whole blood test samples were spiked with possible interfering substances at concentrations equal to or greater than the guideline. Each whole blood sample was tested at two G6PD enzymatic activity levels: normal G6PD activity (>7.0 U/gHb) and near the medical decision level (2.0–4.0 U/gHb). Spiked samples (test pools) were compared to control pool without the interfering substances.

Hematocrit values greater than 40% did not interfere with the G6PD test result. A bias of -15.3% was observed for a normal sample at 29% hematocrit (8.9 g/dL hemoglobin on FINDER) as compared to the control pool of 50% hematocrit (15.3 g/dL hemoglobin on FINDER). A bias of -11.1% was observed for a sample near the medical decision level at 30% hematocrit (11.3 g/dL hemoglobin on FINDER) as compared to the control pool of 50% hematocrit (15.3 g/dL hemoglobin on FINDER).

Exogenous Substances

Substance	Maximum Concentration Tested
Bilirubin-unconjugated	50 mg/dL
Hemoglobin	5 g/L
Intralipid	1000 mg/dL
Glucose	55 mM
Galactose	1 mM
Copper	0.150 mg/dL
Lactate	90 mg/dL
Lactate dehydrogenase	6000 U/L

Common Drugs

Substance	Maximum Concentration Tested
Ampicillin	0.16 mM
Ibuprofen	2.5 mM

4. Assay Reportable Range:
   1.1 U/gHb to 19.7 U/gHb.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   (1) Traceability: The G6PD assay on the FINDER G6PD Cartridge is traceable to NADPH extinction coefficient of 6.3 $mM^{-1}cm^{-1}$.

   (2) FINDER G6PD Test Cartridge Shelf-Life Stability:
   The shelf-life stability was conducted as per EP25-A at one internal site. Real-time stability studies were conducted at 2–8°C at different time points (0, 1, 2, 3, 4, 6, 8, 10, 12, 17, 21, 27, 39, 40, 50, 68, 77 and 83 weeks) using three lots of FINDER G6PD Test Cartridges. Five replicates of two hemolysate controls (G6PD Low and G6PD high) were tested on six FINDER instruments. The expiry date for FINDER G6PD Test Cartridges is currently set at 77 weeks at 2–8°C based on the results of the real-time stability study.

   (3) FINDER G6PD Test Cartridge Pouch Stability:
   In-Use/Open Pouch Stability
   An in-use/open pouch stability study was conducted at one internal site. One control hemolysate sample (G6PD high) was tested at 0, 1 and 2 hours with three lots of FINDER G6PD Test Cartridges at room temperature (18–25°C) after its removal from the foil pouch. Six replicates were tested for each time point on six FINDER instruments.

The storage conditions ranged from 19.4–20.1°C at 24.3–27.9 %RH. The data supports the open pouch (cartridge outside of the foil) stability of one hour at room temperature.

In-Use Unopened Pouch Stability
A real-time stability study to determine the storage stability at room temperature of the unopened cartridge in the foil pouch was performed. The study evaluated FINDER G6PD Test Cartridges stored at the upper end of room temperature (~30°C) using two levels of hemolysate samples, G6PD high and G6PD intermediate. Five replicates of each sample at each time point (0, 4, 8 and 10 hours) were tested. Cartridge in-use stability in an unopened foil pouch was determined to be eight hours at room temperature.

(4) Sample Stability
Two different sample stability studies were conducted at one internal site. Five venous whole blood samples from healthy adults collected in lithium heparin tubes were measured with FINDER G6PD test under refrigerated storage (2–8°C) for up to 77 hours and at room temperature (18–25°C) for up to 4 hours. One lot of FINDER G6PD cartridge was used in this study. Three replicates of each sample were tested at each time point on six FINDER instruments.

Another sample stability study was conducted to include additional G6PD deficient samples: one sample near the medical decision level (3.1 U/gHb) and one deficient sample (<2.0 U/gHb). The real-time sample storage stability was determined by evaluating venous whole blood samples collected in lithium heparin tubes and stored at both room temperature (18–25°C) and refrigerated conditions (2–8°C). Each sample was analyzed on the FINDER for a total of six replicates for each of the five time points tested. The study was performed with one cartridge lot at a single site.

Both studies support the whole blood sample stability of one hour stored at room temperature (18–25°C) and 71 hours under the refrigerated condition (2–8°C).

(5) Controls
Performance of the FINDER system can be verified by analyzing commercially available off-the-shelf hemolysate quality control materials.

6. Detection Limit:
The Limit of Blank (LoB), Limit of Detection (LoD), and the Limit of Quantitation (LoQ) for the FINDER G6PD test were evaluated in accordance with CLSI EP17-A2. The studies were conducted using three lots of FINDER G6PD Cartridges on six FINDER instruments at one internal site. The LoB was evaluated using samples with blank G6PD activity. The LoD was evaluated using samples at low G6PD activity. The LoQ was evaluated using four whole blood samples with increasing levels of G6PD activity prepared by spiking a blank pool with increasing concentrations of a normal pool.

Detection Capability	**G6PD (U/gHb)**
Limit of Blank (LoB)	0.2
Limit of Detection (LoD)	0.4
Limit of Quantification (LoQ)	1.1

7. Assay Cut-Off:
   Not applicable

8. Accuracy (Instrument):
   Not applicable

9. Carry-Over:
   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:
   A method comparison study was performed utilizing CLSI EP09-c.
   Lithium heparinized whole blood samples from 200 subjects collected across six collection sites. Subjects included 89 males and 92 females within the age range of 20–72 years. The samples were analyzed using FINDER G6PD Cartridges on the FINDER instrument. A total of 12 point-of-care operators and five clinical laboratory operators conducted the study across four sites. Whole blood samples were shipped to a central laboratory under refrigerated conditions to analyze samples using the Pointe Scientific G6PD assay on a Cobas Mira instrument. G6PD activity results were compared using a Deming Regression linear fit.

Measurand	N	Range	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
G6PD	200	1.1 – 16.6 U/gHb	0.92 (0.89, 0.95)	0.28 (0.12, 0.44)	0.9

A concordance analysis was performed where the first 36 normal male samples were used to calculate the adjusted male median (AMM). The remaining 167 samples were normalized to AMM and used in the data analysis. The AMM for the FINDER G6PD Test was 10.45 U/gHb. The AMM for the Pointe Scientific G6PD test was 10.88 U/gHb.

The following tables summarize the agreement between the FINDER G6PD Test and the Pointe Scientific G6PD Test (on COBAS) using different cutoffs.

		Pointe Scientific on COBAS			Total	Agreement	Wilson Score 95% CI	
		<30%	30 to 70%	> 70%				
FINDER G6PD Test	<30%	28	2	0	30	100.0%	87.9%	100.0%
	30 to 70%	0	22	2	24	68.8%	51.4%	82.1%
	> 70%	0	8	105	113	98.1%	93.4%	99.5%
	Total	28	32	107	167	92.8%	87.9%	95.8%

		Pointe Scientific on COBAS			Total	Agreement	Wilson Score 95% CI	
		<30%	30 to 80%	> 80%				
FINDER G6PD Test	<30%	28	2	0	30	100.0%	87.9%	100.0%
	30 to 80%	0	31	6	37	70.5%	55.8%	81.8%
	> 80%	0	11	89	100	93.7%	86.9%	97.1%
	Total	28	44	95	167	88.6%	82.9%	92.6%

		Pointe Scientific on COBAS		Total	Agreement	Wilson Score 95% CI	
		<30%	≥30%				
FINDER G6PD Test	<30%	28	2	30	100.0%	87.9%	100.0%
	≥30%	0	137	137	98.6%	94.9%	99.6%
	Total	28	139	167	98.8%	95.7%	99.7%

		Pointe Scientific on COBAS		Total	Agreement	Wilson Score 95% CI	
		<70%	≥70%				
FINDER G6PD Test	<70%	52	2	54	86.7%	75.8%	93.1%
	≥70%	8	105	113	98.1%	93.4%	99.5%
	Total	60	107	167	94.0%	89.3%	96.7%

		Pointe Scientific on COBAS		Total	Agreement	Wilson Score 95% CI	
		<80%	≥80%				
FINDER G6PD Test	<80%	61	6	67	85.9%	76.0%	92.2%
	≥80%	10	90	100	93.8%	87.0%	97.1%
	Total	71	96	167	90.4%	85.0%	94.0%

2. Matrix Comparison:
   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable

2. Clinical Specificity:
   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The reference range study was conducted with 136 healthy subjects. The 95% reference range was determined to be 7.1–14.1 U/gHb for the FINDER G6PD test.

F Other Supportive Instrument Performance Characteristics Data:

1. FINDER G6PD Cartridge Packaging Validation, Environmental/Transit Testing

   The study was conducted to verify the FINDER cartridge transit packaging meets the packaging requirements as defined by the FINDER Product Requirements Document when subjected to summer/winter shipping conditions. Six transit packages of cartridge cartons were used in this study and each carton holds 16 individual cartridges. The packaging validation study demonstrated that no significant damage was sustained on the transit package, the cartridge cartons, or the individually packaged cartridges. The cartridge transit packaging successfully maintained cartridges at 2–25 °C while exposed to the-applied testing temperatures (-10–35 °C)

2. FINDER Instrument Packaging Validation, Environmental/Transit Testing

   The study was conducted to verify the FINDER instrument meets environmental and transit requirements when subjected to different humidity levels (30 %RH and 80 %RH), temperatures (-10–35°C), altitude (0 to 2000 meters), transit shock and vibration conditions. All tests successfully passed with no effect on performance or noticeable damage occurring. The transit/environmental test conditions are claimed as: -10–35°C, 30 %RH to 80 %RH, up to 2000 meters above mean sea level for the storage and transit conditions.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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