Accelerating G6PD Deficiency Diagnosis with Baebies FINDER for Pre-Discharge, In-Hospital Testing

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BACKGROUND

- Glucose-6-phosphate dehydrogenase (G6PD) deficiency is a risk factor for kernicterus (i.e., bilirubin induced neurological damage) in jaundiced newborns and hemolysis following oxidant stress exposure.
- While the state of New York mandated newborn screening for G6PD deficiency in 2022 for certain clinical presentations, most hospitals are not equipped for such testing and samples are sent to reference laboratories.
- Send-out is not optimal for making urgent clinical decisions for treating jaundice and providing results prior to newborn discharge.
- The Baebies FINDER point-of-care G6PD test (FINDER G6PD) provides G6PD enzyme activity values within 17 minutes using 50 µL of whole blood, providing timely results for all patients.

METHODS

- A total of 120 individuals (62 females and 58 males) were recruited for the reference range study; however, 2 samples were excluded because they demonstrated deficiency. Based on the remaining 118 samples, the reference interval was determined using the transformed parametric method in EP Evaluator.
- Intra-run precision was determined from 20 runs of 2 levels of quality control (QC).
- Turnaround time (TAT), the time from sample collection to result reporting, and the prevalence of G6PD deficiency in the patient population were determined for two 6-month intervals: December 1, 2023 – May 31, 2024, when samples were sent out to the reference laboratory, and July 1, 2024 – December 31, 2024, when samples were tested in the hospital laboratory with FINDER G6PD.

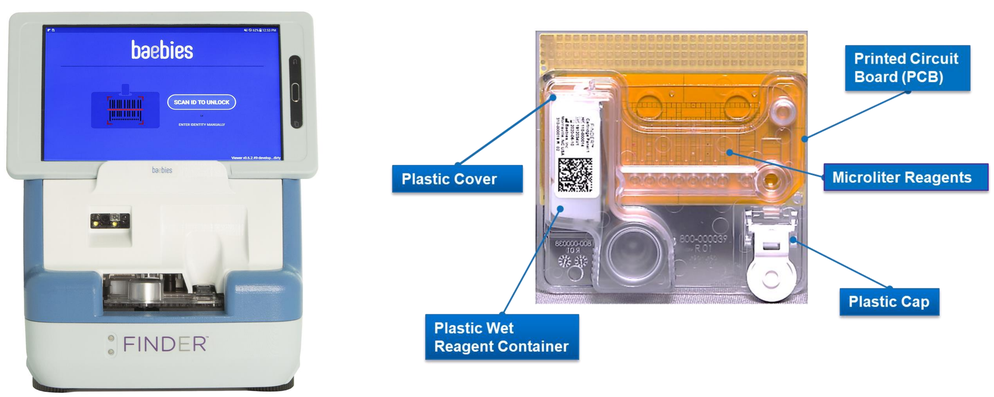

Figure 1: Baebies' FDA-cleared, point-of-care FINDER® instrument and cartridge for G6PD testing.

RESULTS

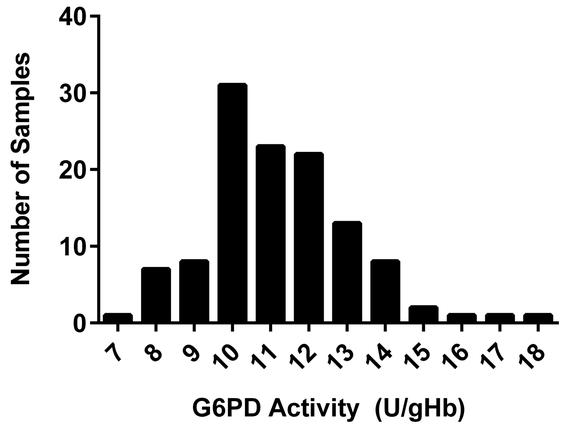

Figure 2: Reference interval is 8.0 U/gHb – 15.2 U/gHb.

Intra-run Precision			
QC Level	Mean (U/gHb)	SD	CV (%)
Normal	12.7	0.47	3.7
Abnormal (Low)	5.6	0.18	3.3

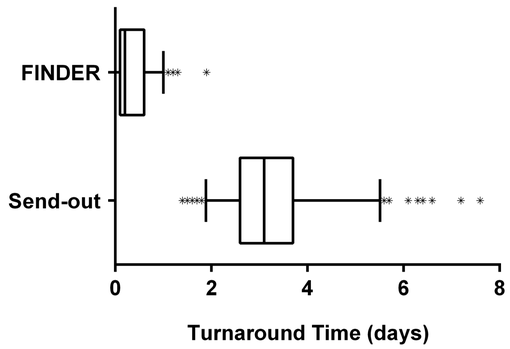

Figure 3: Median turnaround time for reference laboratory testing was 75.4 hours (3.1 days) compared to 4.5 hours (0.2 days) for FINDER G6PD in-hospital laboratory testing.

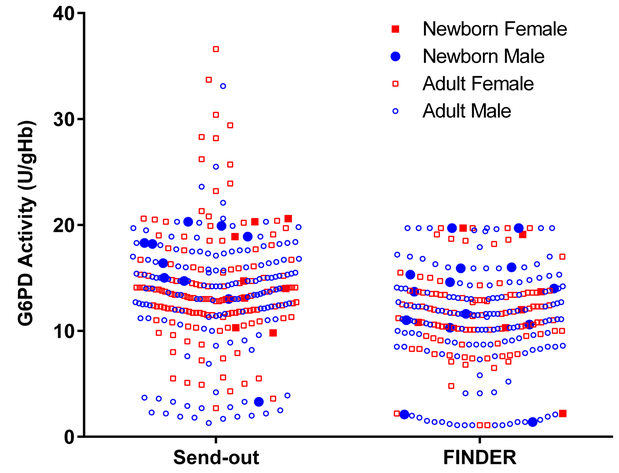

Figure 4: G6PD deficiency prevalence was 15.5% (43/277) for all patients tested and 11.1% (2/18) for newborns (i.e., patients ≤1 month) in send-out reference laboratory testing. G6PD deficiency prevalence was 17.9% (43/240) for all patients tested and 14.3% (3/21) for newborns in FINDER G6PD in-hospital laboratory testing.

CONCLUSIONS

- **Hospital laboratory testing using FINDER G6PD provides results in 4.5 hours compared to 3.1 days, ensuring G6PD diagnosis prior to hospital discharge of newborns.**
- **This rapid TAT enables real-time decision-making, allowing timely interventions, including treatment and education for G6PD-deficient newborns.**
- **The prevalence of G6PD deficiency in the population served by New York Presbyterian Hospital-Columbia University Irving Medical Center is high, demonstrating the need for G6PD testing results for patient care.**
- **Other patients, such as those being evaluated for possible treatment with medications contraindicated in individuals with G6PD deficiency (e.g., rasburicase), also benefit from more rapid testing results.**