Diagnostics Instrument–Target Product Profile

Diagnostic Instrument: Hemoglobinometer

Version 1.1–June 2018
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# Executive summary

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<tr>
<td><strong>Product use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended use</td>
<td>The diagnostic device is intended to measure blood hemoglobin (Hb) concentration. The test will provide results expressed in grams Hb per deciliter and must clinically differentiate mild, moderate, and severe anemia.</td>
<td>Same.</td>
</tr>
<tr>
<td>Target population</td>
<td>Pregnant women receiving care at antenatal care (ANC) clinics.</td>
<td>Pregnant women receiving ANC in all settings, postpartum women (0–6 months after delivery), and prepregnancy girls and women.</td>
</tr>
<tr>
<td>Infrastructure level</td>
<td>ANC clinics in community health facilities, district health facilities and hospitals, and regional hospitals. Tier 4 health care settings and above (WHO heath facility classifications).</td>
<td>All health care settings where women seek care during the pre- and postnatal period, including through mobile clinics and home visits.</td>
</tr>
<tr>
<td>Target countries</td>
<td>All countries categorized by WHO as having severe (&gt;40% prevalence) or moderate (20%–39% prevalence) anemia public health problems.</td>
<td>All countries where antenatal services are provided in settings without access to full blood-count testing.</td>
</tr>
</tbody>
</table>

**Product performance**
<table>
<thead>
<tr>
<th>Variable</th>
<th>Minimum</th>
<th>Optimistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical sensitivity and specificity</td>
<td>Sensitivity $\geq$85% and specificity $\geq$80% in each trimester of pregnancy at the moderate anemia threshold of 11.0g/dL and the severe anemia threshold point of 7.0g/dL.</td>
<td>Sensitivity $\geq$95% and specificity $\geq$90% in each trimester of pregnancy at the moderate anemia threshold of 11.0g/dL and the severe anemia threshold point of 7.0g/dL.</td>
</tr>
<tr>
<td>Precision</td>
<td>Coefficient of variation (CV) should not exceed 6%.</td>
<td>To be determined.</td>
</tr>
<tr>
<td>Analytical accuracy relative to reference method</td>
<td>In comparison to the standard reference, 80% of the results must fall within $\pm$1.0g Hb/dL of the reference across the range of Hb concentrations.</td>
<td>In comparison to the standard reference, 85% of the results must fall within $\pm$1.0g Hb/dL of the reference across the range of Hb concentrations.</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>The device should be able to operate at $15^\circ$C–$35^\circ$C, 30%–85% humidity.</td>
<td>The device should be able to operate at $15^\circ$C–$40^\circ$C, 20%–90% humidity.</td>
</tr>
<tr>
<td>Product design</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complexity</td>
<td>No more than 5 steps. Requires one health worker to execute.</td>
<td>No more than 3 steps. Requires one health worker to execute.</td>
</tr>
<tr>
<td>Instrumentation</td>
<td>Handheld, portable reader device and disposable/consumable component (less than 500 grams).</td>
<td>Handheld portable device with no consumables.</td>
</tr>
<tr>
<td>Variable</td>
<td>Minimum</td>
<td>Optimistic</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Sample type</td>
<td>Capillary blood from fingerstick and venous whole blood collected in anticoagulant.</td>
<td>Noninvasive device: none.</td>
</tr>
<tr>
<td>Sample collection and processing</td>
<td>Finger prick using a standardized lancet or venipuncture with no sample processing.</td>
<td>Noninvasive sensor probe: none.</td>
</tr>
<tr>
<td>Quality control</td>
<td>Manufacturer provides controls specific for test in intended use</td>
<td>Compatible with commercial hemoglobin controls. Clear instructions for quality controls appropriate for intended use.</td>
</tr>
</tbody>
</table>

**Costs and channels to market**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Channel(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target cost per result</td>
<td>Less than US$0.75 cents. Includes the consumable cost plus the reader cost per result.</td>
<td>To be determined.</td>
</tr>
<tr>
<td>Channels to market</td>
<td>Through UNICEF Supply Division, Unitaid, and the Global Financing Facility. Additionally, local distributors to procure the consumable components locally.</td>
<td>Same.</td>
</tr>
</tbody>
</table>

*HemoCue is a registered trademark of HemoCue AB, Angelholm, Sweden.
Product use summary / medical need / differentiation strategy

**Clinical and/or surveillance need:**
Improving the nutritional status of women before and during pregnancy can reduce the risk of adverse birth outcomes. Anemia is a significant driver of poor nutritional status and the global prevalence of anemia among pregnant women is about 38%. Clinical assessment is a common but inaccurate method for detecting anemia. Laboratory-based methods, such as an automated hematology analyzer, are unsuitable for use in antenatal care (ANC) settings. Currently available point-of-care tests are considered expensive, and the high cost can prohibit routine use. There is a need for a point-of-care (POC) hemoglobinometer for routine screening of pregnant women for anemia in all health settings where women seek ANC. More accurate and reliable anemia-detection tools will support better clinical decision-making, help stratify pregnant women according to their risk of anemia-related pregnancy complications, and potentially improve provider and patient compliance with recommended anemia treatment options, such as iron-folic acid supplementation.

**Intended use case scenario:**
A low-cost POC hemoglobinometer will be used for routine screening in ANC clinics. The 2016 World Health Organization (WHO) recommendations on ANC for a positive pregnancy experience recommends routine anemia testing at weeks 12, 26, and 36 in countries where the prevalence of anemia is at least 40% among pregnant women. The test will evaluate hemoglobin (Hb) concentration in capillary blood as part of routine screening at ANC and at delivery. The test will identify women with all severity levels of anemia (mild, moderate, severe) and provide accurate results to inform treatment options and monitor hemoglobin concentration throughout pregnancy. Trained clinicians and facility-based health workers, including nurses and midwives as well as trained community health workers, will use the test in all health settings where women seek ANC, primarily in ANC clinics.
### Target populations and use cases

<table>
<thead>
<tr>
<th>Target</th>
<th>Annotation</th>
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</thead>
<tbody>
<tr>
<td><strong>3.1 Intended Use</strong></td>
<td>A robust, low-cost, accessible, and accurate point-of-care (POC) Hb measurement tool would enable routine anemia screening within the antenatal care (ANC) programs in low- and middle-income countries (LMIC).</td>
</tr>
</tbody>
</table>

The diagnostic device is intended to measure blood hemoglobin (Hb) concentration. The test will provide results expressed in grams Hb per deciliter and must clinically differentiate mild, moderate, and severe anemia.

This diagnostic must be able to discriminate between healthy women and women with mild anemia, moderate anemia, and severe anemia with sufficient accuracy to support clinical decision-making. While this diagnostic must identify all cases of anemia (<11.0g/dL) to ensure adequate treatment and follow-up is received, the priority is to identify all cases of severe anemia (<7.0g/dL). The results will be used to inform treatment options, including an iron and folic acid (IFA) supplementation regimen. Depending on the severity of anemia and the time of testing, women may receive IFA supplements, counseling, and treatment regarding malaria or deworming and iron intravenous or intramuscular injections. The result may also be used to facilitate referral for treatment at a higher-tier health facility.

ANC is delivered in both the public and private health sectors.² ANC is commonly provided in primary health facilities. As such, the test will need to provide a result at the POC and be no more complex than current components of ANC care, such as blood pressure measurement or malaria rapid tests.

Screening may be achieved through invasive tests that require a blood sample or noninvasive tests that require no sample. Some literature and clinical experts report that noninvasive devices have significant performance limitations that limit their utility in clinical decision-making.³⁴⁻⁵
### 3.2 Target Population

**Minimum:** Pregnant women receiving care at ANC clinics.

**Optimistic:** Pregnant women receive care in all ANC settings (home, mobile, and community clinics), postpartum women (0–6 months after delivery), and prepregnancy girls and women.

The primary target is pregnant women undergoing routine ANC visits at primary clinics in LMIC. The 2016 WHO recommendations on ANC for a positive pregnancy experience recommends routine anemia testing at weeks 12, 26, and 36 in countries where the prevalence of anemia is at least 40% among pregnant women. If there is no Hb result on record, Hb should be checked when pregnant women arrive at a birthing facility for delivery in order to understand risk of postpartum haemorrhage.

In addition to routine ANC, the test may also be used outside of clinic settings and in populations before and after pregnancy. Stakeholders interviewed reported an interest in expanding anemia screening to the prepregnancy and postnatal period and through screening in school settings and during postpartum care.

### 3.3 End Users

**Minimum:** Facility-based health care workers: nurses, medical officers, and midwives.

**Optimistic:** Facility and community-based health care workers.

End users of the test will vary across countries and facility types. All users will receive training in the use of the test along with other components of routine screening in ANC. ANC services at facilities are generally delivered by nurses, medical officers, clinical officers, and midwives. A formative usability assessment in a representative ANC setting in Ghana found that end users ranged from community health nurses to laboratory technicians with between 2 and 5 years of medical training.

Optimistically, a POC Hb measurement tool would be sufficiently robust and simple to use outside of the ANC clinic setting. This would expand access to anemia testing in the prepregnancy and postnatal period through home visits and community- and school-based screening and entail use by lower-skilled community health workers.

### 3.4 Infrastructure Level

This diagnostic will be used at primary care clinics and other health facilities where ANC is provided, such as district hospitals or facilities with limited or
**Minimum:** ANC clinics in community health facilities, district health facilities and hospitals, and regional hospitals. Tier 4 health care settings and above (WHO health facility classifications).

**Optimistic:** All health care settings where women seek care during the pre- and postnatal period, including through mobile clinics and home visits.

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<table>
<thead>
<tr>
<th>3.5 Target Countries</th>
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<tbody>
<tr>
<td><strong>Minimum:</strong> All countries categorized by WHO as having severe (≥40% prevalence) or moderate (20%–39% prevalence) anemia public health problems.</td>
<td>All countries with severe or moderate prevalence of anemia in pregnant women would benefit from a POC Hb measurement tool to expand access to screening in ANC and reduce the burden of maternal anemia. Globally, in countries with a lower prevalence of anemia, a POC hemoglobin measurement tool will expand access to anemia screening in settings without access to full blood-count testing.</td>
</tr>
<tr>
<td><strong>Optimistic:</strong> All countries where antenatal services are provided in settings without access to full blood-count testing.</td>
<td>As a target launch country, India is well suited in terms of health need and policy alignment. The prevalence of anemia during pregnancy in India is one of the highest globally, estimated at 59%. Operational guidelines to reduce the prevalence of anemia in India among all at-risk groups include the use of digital hemoglobinometers, indicating an opportunity to introduce and scale hemoglobin measurement tools.</td>
</tr>
</tbody>
</table>

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1. no laboratory capacity. Full blood-count testing is recommended in facilities where this level of laboratory capacity is present.

2. Optimistically, a POC Hb measurement tool would be sufficiently robust and simple to use outside of the ANC clinic setting. This would expand access to anemia testing in the prepregnancy and postnatal period through home visits and community- and school- based screening and entail use by lower-skilled community health workers.

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8. As a target launch country, India is well suited in terms of health need and policy alignment. The prevalence of anemia during pregnancy in India is one of the highest globally, estimated at 59%. Operational guidelines to reduce the prevalence of anemia in India among all at-risk groups include the use of digital hemoglobinometers, indicating an opportunity to introduce and scale hemoglobin measurement tools.
### 3.6 Target Customer

Public and private clinics that provide ANC services. In order for diagnostics to be procured and used in public ANC clinics, they must be registered in-country and be included on lists of products that can be covered by the national health insurance program. A hemoglobinometer is included in the World Health Organization Model List of Essential In Vitro Diagnostics.

### Additional comments:

**Fit with clinical workflow / linkage to care.**

A low-cost POC hemoglobinometer would enable routine screenings of Hb concentration among pregnant women at 12, 26, and 36 weeks, as per WHO recommendations, and be offered for free as part of ANC. There are geographic summaries of anemia prevalence in pregnant women globally.
some reports of women being asked to pay for the cost of screening in a laboratory. Anemia screening and use of the hemoglobinometer will be done in parallel with other recommended ANC screening practices included in global and national guidelines. Health workers using the diagnostic need to be able to read the result of the test and interpret it in the context of the relevant anemia thresholds and other clinical indicators and measurements taken during ANC.

Providers will conduct the test at the POC. The result must be available immediately and used to communicate the hemoglobin measurement value and anemia status. The result will be used to inform treatment options, including iron and folic acid (IFA) supplementation regimen. Depending on the severity of anemia and the time of testing, women may receive IFA supplements, counseling, and treatment regarding malaria or deworming and iron intravenous or intramuscular injections. The result may also be used to facilitate referral for treatment at a higher-tier health facility.
## Target performance

<table>
<thead>
<tr>
<th>Target</th>
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<tbody>
<tr>
<td><strong>4.1 Clinical Sensitivity and Specificity</strong></td>
<td>This diagnostic must discriminate between healthy individuals, mild anemia, moderate anemia, and severe anemia with sufficient accuracy to support clinical decision-making, as in routine ANC there will be limited or no access to confirmatory testing.</td>
</tr>
<tr>
<td><strong>Minimum:</strong> Sensitivity ≥85% and specificity ≥80% in each trimester of pregnancy at the moderate anemia threshold of 11.0g/dL and the severe anemia threshold point of 7.0g/dL.</td>
<td>Evidence generated in multiple studies and reviewed by WHO found that some POC hemoglobin measurement techniques have sufficient performance to improve detection of anemia in pregnancy.\textsuperscript{12-14} Expert interviews indicated that sensitivity is prioritized over specificity to identify cases of anemia and, in particular, all cases of severe anemia.\textsuperscript{6} Some evidence suggests that Hb measurement tools, particularly noninvasive tools, may have insufficient performance—specifically, decreased accuracy in the second or third trimester due to changes in circulatory status.\textsuperscript{3} There may be a need for further evidence to inform the risk and the cost of both over- and underestimating anemia in pregnant women.</td>
</tr>
<tr>
<td><strong>Optimistic:</strong> Sensitivity ≥95% and specificity ≥90% in each trimester of pregnancy at the moderate anemia threshold of 11.0g/dL and the severe anemia threshold point of 7.0g/dL.</td>
<td></td>
</tr>
<tr>
<td><strong>4.2 Precision</strong></td>
<td>Hb concentration in capillary blood likely varies more than in venous blood due to the variable presence of interstitial fluids. This variation may be compounded by varying finger-prick techniques that may impact precision measurements.\textsuperscript{14} The standard reference for capillary measurement—the HemoCue®—reports CV ranging from 0.51-1.3%.\textsuperscript{15} This variation may be addressed through repeat measurements, which may be facilitated by multiple ANC visits over the course of the pregnancy.</td>
</tr>
<tr>
<td><strong>Minimum:</strong> Coefficient of variation (CV) should not exceed 6%.</td>
<td></td>
</tr>
<tr>
<td><strong>Optimistic:</strong> To be determined.</td>
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</tbody>
</table>
Minimal and optimistic precision criteria may warrant further study. The criteria reported here take into account the precision estimates of the standard reference for capillary measurement. The optimal precision criteria should be a judgement of the corresponding clinical risk associated with missing someone with severe anemia or the cost to the health system of overestimating anemia prevalence or severity.

### 4.3 Analytical Accuracy Relative to Reference Method

**Minimum:** In comparison to the standard reference, 80% of the results must fall within $\pm 1.0$g Hb/dL of the reference across the range of hemoglobin concentrations.

**Optimistic:** In comparison to the standard reference, 85% of the results must fall within $\pm 1.0$g Hb/dL of the reference across the range of hemoglobin concentrations.

The clinically acceptable bias is within 1.0g/dL of the reference across the dynamic range of Hb concentrations ($4 - 17$g/dL).

The POC results should be strongly correlated with reference standard with a correlation coefficient $>0.80$.

Mean difference (bias) should be less than or equal to $+0.5$g/dL. Absolute mean difference should be less than 1.0g/dL in each trimester.

### 4.4 Limit of Detection

**Minimum:** Clinically relevent threshold of 4g Hb/dL or lower.

**Optimistic:** Same.

This diagnostic must be able to discriminate between healthy women and women with mild anemia, moderate anemia, and severe anemia to inform linkage to care. Global and national clinical guidelines indicate that measurements below 4 grams Hb/dL do not indicate different clinical management strategies. The hemoglobin measurements below 4 g/dL require blood transfusion.

### 4.5 Time to Result

**Minimum:** 5 minutes or less.

**Optimistic:** 2 minutes or less.

The time to result should be comparable with other diagnostics used in ANC. This may include blood pressure measurements and rapid diagnostic tests for HIV or malaria, which entail a 10–15 min time to result. The HemoCue® requires 15–60 seconds to a result.

### 4.6 Throughput

**Minimum:** 1 sample per test run.

In an ANC setting, a provider will see one patient at a time. The volume of patients attending ANC will vary across facilities. One study in a
**Optimistic**: Same.

<table>
<thead>
<tr>
<th>4.7 Operating Temperature</th>
<th>In a study monitoring the temperature and humidity at surveillance sites in four African countries, the mean and median operating temperatures were 26.6°C and 26.4°C, respectively, with a range of 17.6°C–37.0°C. For the same sites the mean and median relative humidity values were 70.4% and 72.1%, with a range of 40.2% to 119.5%. These are similar to expected conditions in ANC clinics in intended-use settings. Recent field testing in ANC clinics suggest that technologies used in ANC need to be robust to extreme environmental conditions, including temperatures of about 35.0°C. Certain models of the HemoCue® for POC capillary testing are more robust to extreme temperatures than others.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minimum</strong>: The device should be able to operate at 15°C–35°C, 30%–85% humidity.</td>
<td><strong>Optimistic</strong>: The device should be able to operate at 15°C–40°C, 20%–90% humidity.</td>
</tr>
<tr>
<td><strong>4.8 Reference Methods</strong></td>
<td>The test should be comparable to reference standing using both capillary blood (HemoCue®) and venous blood (automated analyzer). There is extensive data demonstrating the accuracy of the HemoCue® compared to the reference automated hematology analyzer. However, sufficient differences are also evident and, if possible, both methods should be used as reference methods to triangulate.</td>
</tr>
</tbody>
</table>
| **Minimum**: Standard reference method for capillary or venous blood:  
1. HemoCue (capillary blood samples).  

*HemoCue is a registered trademark of HemoCue AB, Ängelholm, Sweden.
### 5.1 Complexity

**Minimum:** No more than 5 steps. Requires only one health worker to operate.

**Optimistic:** No more than 3 steps. Requires only one health worker to operate.

If an invasive test is used, the trained health care worker will use an alcohol wipe to clean the finger. A lancet will be used to prick the finger to obtain a capillary blood sample, applied to the test device. The hemoglobin diagnostic will then measure the blood sample. A noninvasive test will require fewer steps but may require navigating digital interface. The device must be appropriate for the setting with respect to cost, resources required, human capacity, and usability/acceptability. Ease of use is a critical feature for widespread adoption of diagnostic technologies in low-resource settings.

### 5.2 Instrumentation

**Minimum:** Handheld, portable reader device and disposable/consumable component for individual measurement.

**Optimistic:** Handheld portable device with no consumables.

Instrumentation for an invasive test includes a reader plus consumables, a strip or a cuvette. Instrumentation for noninvasive test includes a digital device either with or without a probe with a sensor. If a noninvasive test is used, the instrument might be a mobile platform that includes other diagnostics, clinical support tools, or decision-making algorithms. The complexity of clinical algorithms in antenatal care (ANC) settings are well suited to translation to a digital platform and could improve ANC service delivery and health outcomes. Instruments must be robust devices, resilient to high heat, humidity, and dusty environments.

### 5.3 Power Requirements

**Minimum:** AC adapter for running on power with battery backup.

**Optimistic:** Same.

Some ANC facilities do not have electricity and will require battery-operated devices that can operate during all ANC hours (sometime more than 8 hours per day).

### 5.4 Quality Control

**Minimum:** Manufacturer provides controls configured appropriately for intended use.

Some commercially available controls may require cold chain or other infrastructure. Controls need to be able to be used in the same setting by the same target end user of the test.
**Optimistic:** Compatible with commercial hemoglobin controls and clear instructions for use, appropriate for use in low- and middle-income countries (LMIC) ANC settings.

### 5.5 Time to Result

**Minimum:** 5 minutes or less.

**Optimistic:** 2 minutes or less.

The time to result should be comparable with other diagnostics used in ANC settings. This may include blood pressure measurements and rapid diagnostic tests for HIV or malaria. The standard reference for capillary measurement requires 15–60 seconds to a result.\(^{15}\)

### 5.6 Throughput

**Minimum:** 1 sample per test run.

**Optimistic:** Same.

In an ANC setting, a provider will see one patient at a time. The volume of patients attending ANC will vary across facilities. One study in a representative ANC setting found that a provider may see up to 8 women per day and thus run up to 8 tests per day, though others may see significantly more.\(^{25}\)

### 5.7 Sample Type

**Minimum:** Capillary blood from fingerstick and venous whole blood collected in anticoagulant.

**Optimistic:** Noninvasive device: none.

In order to demonstrate performance and validate tests for the ANC intended use, invasive devices must be run using capillary blood collected through fingerstick. Noninvasive devices will require no specimen and can more easily obtain repeat measurements, suggested in some testing protocols.\(^{14}\) However, some literature and clinical experts report that noninvasive devices have significant performance limitations that limit their utility in clinical decision-making. More performance data on noninvasive devices is needed.\(^{3–5}\)

### 5.8 Sample Collection and Processing

**Minimum:** Finger prick or venipuncture with no sample processing.

**Optimistic:** Noninvasive sensor probe: none.

Test should be resilient to varying finger-prick and blood-application techniques between users.\(^{14}\)

### 5.9 Sample Volume

**Minimum:** One blood drop (10uL).

**Optimistic:** Noninvasive: none.

The size of the blood drop must not influence the hemoglobin concentration result. Alternatively, the device must have a mechanism to standardize the amount of blood read by the device. PATH experiments with 2, 5, 10, and 20 uL indicated that the size of the blood drop may influence the hemoglobin measurement. If blood-drop size does influence the result, then the device
<table>
<thead>
<tr>
<th>Section</th>
<th>Minimum</th>
<th>Optimistic</th>
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</thead>
<tbody>
<tr>
<td>5.10 Target Analyte</td>
<td><strong>Minimum:</strong> Hemoglobin concentration</td>
<td>Expert interviews indicated that clinicians would greatly benefit from a diagnostic that, in addition to Hb measurement, provided additional information regarding the root cause of anemia among ANC patients. This might include infection, malaria, and/or hemoglobinopathies or dietary deficiencies of iron, folate, and vitamin A.</td>
</tr>
<tr>
<td></td>
<td><strong>Optimistic:</strong> Same</td>
<td></td>
</tr>
<tr>
<td>5.11 Calibration</td>
<td><strong>Minimum:</strong> Manufacturer provides all required calibration and specifics when and how device must be calibrated.</td>
<td>Readers with disposable strips may need to be recalibrated when a new lot is used or at other regular intervals. A digital device may require no calibration.</td>
</tr>
<tr>
<td></td>
<td><strong>Optimistic:</strong> No calibration needed.</td>
<td></td>
</tr>
<tr>
<td>5.12 Data Handling</td>
<td><strong>Minimum:</strong> None.</td>
<td>Data-management method will need to be compatible with local record system. Many settings use an ANC booklet kept by patient that tracks pregnancy health record during and between pregnancies. The device output, including any digital version of the results, should be compatible with local systems.</td>
</tr>
<tr>
<td></td>
<td><strong>Optimistic:</strong> Up to 500 previous test results would be stored on device and downloaded via USB or other connection.</td>
<td></td>
</tr>
<tr>
<td>5.13 Other Supplies Needed</td>
<td><strong>Minimum:</strong> Lancets and alcohol swabs.</td>
<td>Apart from supplies to conduct blood sample collection, the kit should contain all necessary supplies for running the test.</td>
</tr>
<tr>
<td></td>
<td><strong>Optimistic:</strong> None.</td>
<td></td>
</tr>
<tr>
<td>5.14 Waste Disposal</td>
<td><strong>Minimum:</strong> Does not include material that cannot be disposed of in a normal ANC setting.</td>
<td>Disposable strips and other testing supplies could be disposed of using routine methods at primary care clinics.</td>
</tr>
<tr>
<td></td>
<td><strong>Optimistic:</strong> No biohazard waste for disposal.</td>
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</table>
### 5.15 Target Shelf Life

**Minimum:** For disposable component: 3 months upon opening container at test operating range. No cold chain required.

**Optimistic:** None.

| The minimum and optimistic criteria for shelf life will vary depending on whether the test is invasive and requires a reader plus consumables or noninvasive and requires a digital device and possible a sensor/probe. More information is needed to inform these requirements across varying contexts. The shelf life of the HemoCue® (HemoCue AB, Ängelholm, Sweden) is 3 months upon opening container at test operating range with no cold chain requirements. Stakeholder interviews indicate that this is acceptable and aligned with patient volumes in most target settings. A noninvasive test would not have any shelf life restrictions. |
### Target Costs and Channels to Market

<table>
<thead>
<tr>
<th>Target</th>
<th>Annotations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6.1 Target Cost per Result</strong>&lt;br&gt;&lt;br&gt;<strong>Minimum:</strong> Less than US$0.75 per test. Includes the consumable cost plus the reader cost per result.&lt;br&gt;&lt;br&gt;<strong>Optimistic:</strong> To be determined.</td>
<td>Given the test use as part of routine screening at multiple time points during pregnancy, cost is a critical factor. Expert interviews and global guidance acknowledges that proposed use may entail high recurrent costs, and alternatives to a hemoglobinometer may be used if high cost would prohibit routine and regular screening.¹&lt;br&gt;&lt;br&gt;The estimated cost per result using a digital hemoglobinometer is $0.75 (HemoCue®; HemoCue AB, Ängelholm, Sweden), which, given the recurrent cost of screening at multiple timepoints, may be too costly for routine use in ANC.³¹ Stakeholders interviewed indicated that the cost per result should be in the $0.02–$0.07 range.³²,³³ The willingness of manufacturers to meet such low prices points in a relatively undefined market must also be carefully considered.&lt;br&gt;&lt;br&gt;The total cost of the test would include the cost of the reader plus any consumable component. For invasive tests, this would include any disposable strip or cuvette, and for noninvasive tests, this would include any sensor or probes needed. More costing and cost-effectiveness data is needed to understand the minimal and optimistic criteria for test cost. In particular, the different cost structures between an invasive and noninvasive method should be better understood.</td>
</tr>
</tbody>
</table>

| **6.2 Stability Requirements, Storage Conditions, Cold Chain Requirements** | See 5.15 Target Shelf Life. |
### 6.3 Channels to Market

**Minimum:** Approved by relevant global bodies (i.e., UNICEF to enable distribution by UNICEF Supply Division). Any consumables must be available through local distributors in each target country to ensure a consistent supply.

**Optimistic:** Same as well as ability to procure and distribute through the Global Financing Facility (GFF).

Once approved, certified, and accepted by UNICEF, it would be the preferred method, distributed by UNICEF Supply Division. Procurement through GFF. Consumables must be available locally in order to ensure a consistent supply. Two core attributes identified as necessary for hemoglobinometer uptake included user training on test use and maintenance and local availability of disposable components.¹¹

### 6.4 Supply, Service, and Support Mechanisms

**Minimum:** Service and support supplied via distribution channels, either directly from NGOs procuring tests or from their agents/distributors.

**Optimistic:** No service or support required.

Delivery of service and support may come through the product distribution channels. Ideally, the device would not require external service or support for the duration of use. Clear training materials should be made widely available.
References


## Change management

<table>
<thead>
<tr>
<th>Version</th>
<th>Key changes from previous version</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>First draft of the TPP for point-of-care hemoglobinometers.</td>
</tr>
<tr>
<td>1.1</td>
<td>PATH edits based on literature review and stakeholder interviews.</td>
</tr>
<tr>
<td>June 29, 2018</td>
<td></td>
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</tbody>
</table>