Assessing hemoglobinometers for maternal care: landscape analysis of commercial products and late-stage prototypes for anemia screening

August 2018
# Contents

**LANDSCAPE ANALYSIS**

Clinical signs and symptoms

Manual visual comparison

- Hemoglobin color scales
- Sahli’s method
- Manual microhematocrit readers

Portable hemoglobinometers

Noninvasive approaches

- Pronto® and Radical® Devices
- NBM-200
- Haemospect®
- HemaApp
- ToucHb

**REFERENCES**

1

1

1

2

2

3

3

4

4

4

4

4

17
Landscape analysis

There are a number of options available for anemia screening at the point of care. These include clinical examination of signs and symptoms, approaches that utilize manual visual comparison of blood samples, portable hemoglobinometers, and noninvasive approaches. Each is described below, and a subset are compared against key minimum target product profile (TPP) criteria in table 1.

Clinical signs and symptoms

Clinical examination assessing pallor (lightness in appearance) of the conjunctiva, tongue, nailbeds, and palm is a useful strategy for ruling out severe anemia, and to a lesser extent for diagnosing severe anemia.\(^1,2\) It is important to recognize that pallor is by no means a highly accurate clinical sign of anemia,\(^3\) but using this method can be beneficial in resource-constrained settings where severe anemia is common and hemoglobin or hematocrit cannot be determined quantitatively.\(^4\) However, while specificity is high, the low sensitivity of this approach makes it problematic because many severely anemic patients will go undetected. The effectiveness of pallor in assessing anemia is influenced by a number of factors, including which anatomical site is assessed; individual characteristics, such as skin pigmentation, jaundice, or preexisting conjunctivitis; patient hemoglobin levels; and which hemoglobin cutoff values are used.\(^3\) One approach to maximize sensitivity is to examine several anatomical sites and consider pallor at any one of them to be a sign of anemia.\(^5,6\) This approach is supported by the fact that clinical assessment of pallor has no associated cost and sensitivity is the limiting factor in performance.\(^4\) Due to its widespread implementation and feasibility, clinical examination of pallor will likely remain a useful way to assess severe anemia within the context of field work. However, more robust methods and technologies are needed because the shortcomings of using pallor to detect anemia, particularly cases of mild anemia, are well established and clinically relevant. Of note, clinical symptoms of anemia include fatigue and shortness of breath; however, these are not sensitive enough to allow for diagnosis.

Manual visual comparison

A summary table of hemoglobin estimation approaches that utilize manual visual assessment of blood samples can be found in table 2. These include hemoglobin color scales, Sahlí’s method, and microhematocrit readers.

Hemoglobin color scales

In 1995, the World Health Organization (WHO) developed the Hemoglobin Color Scale (HCS) for use in settings where laboratory-based hemoglobin estimation methods are unavailable. The HCS is designed for use in resource-limited settings where anemia would otherwise be diagnosed based on clinical signs as outlined above.\(^7\) According to this method, a drop of blood is placed onto a test strip of specialized chromatography paper. After 30 seconds has passed, the color of the paper is visually compared to a standardized color scale on a card that depicts varying shades of red, corresponding to different concentrations of hemoglobin. The first WHO HCS became commercially available in 2001, manufactured by Copack (Oststeinbek, Germany).\(^7\) The Copack test uses a six-shade reference scale that includes shades of red that correspond to 40-g/L, 60-g/L, 80-g/L, 100-g/L, 120-g/L, and 140-g/L measurements.\(^8\) In addition to the HCS manufactured by Copack, other versions of the scale have also been developed. For
example, the HCS-HLL (Hindustan Lifecare Limited, India) has been adapted specifically for use in the Indian context.\(^9\)

According to a recent systematic review by Marn & Critchley (2016),\(^{10}\) the HCS can improve the accuracy of anemia diagnosis when compared to clinical assessment alone.\(^1\) The HCS is simple, inexpensive, does not require electricity, and requires minimal training. However, it is subject to bias in visual color comparison, requires the use of specialized chromatography paper, and is unable to detect changes in hemoglobin smaller than 10 g/L.\(^{11}\) Additionally, a number of errors can also result from incorrect use of the device. These include reading the scale under inadequate lighting, holding the scale at an incorrect angle, applying too little or too much blood to the test strip, and reading the results too soon (before 30 seconds has passed) or too late (after two minutes has passed).\(^{12}\)

**Sahli’s method**

Another technique for hemoglobin estimation that relies on visual color comparison is Sahli’s method, currently recommended by the Government of India.\(^{13}\) The principle of Sahli’s method involves the conversion of hemoglobin to acid hematin, which is then visually compared against the color of a solid glass standard.\(^{14}\) To perform the test, dilute hydrochloric acid (HCl) is added to a graduated cylinder that contains a 20µL blood sample. HCl is added until the color of the solution matches that of the glass standard, as determined by a visual comparison to be conducted in a room with natural light. Once a color match is determined, the level of fluid in the tube indicates the hemoglobin value. The test takes approximately ten minutes and requires several supplies, including a Sahli hemoglobinometer, a pipette, a stirring rod, dilute 0.1 M HCl, a dropper, and detergent.\(^{14}\) Although Sahli’s method is simple and inexpensive and does not require electricity, it has a number of limitations. Notably, as with the HCS, Sahli’s method is subject to bias due to the subjectivity involved with visual color comparison. Additionally, the accuracy of the test relies upon accurate pipetting and the equipment being cleaned properly between uses, and the materials are prone to wear and breakage. For example, the color of the glass standard can fade over time, particularly when exposed to sunlight.\(^{15,16}\)

**Manual microhematocrit readers**

Hematocrit, or the ratio of red-cell volume to whole-blood volume, can also be determined using manual approaches. According to this method, a capillary sample is collected, placed into capillary tubes with an anticoagulant, and spun in a centrifuge until the sample separates. The tubes are then measured for the height of the sample and that of the packed red-cell layer using a manual microhematocrit reader with a reference chart.\(^{17}\) The height of the red-cell layer is divided by the total sample height to obtain the percentage of red blood cells.\(^{14}\) Although this approach is inexpensive and simple, limitations include the need for a centrifuge, as well as the bias introduced by visual assessment of the sample against the manual reader scale.\(^{18}\) The results can also be influenced by the equipment, including the diameter of the tube, the type of anticoagulant solution, and the type of centrifugation equipment.\(^{19}\) Automated centrifuges that provide a digital reading, such as the HemataStat II (EKF Diagnostics, Cardiff, United Kingdom), have also been developed.\(^{20}\)

---

\(^{1}\) Note: Many different method comparison studies have compared the performance of different anemia screening devices and approaches. However, findings of method-comparison studies are often inconsistent, and studies can be hard to compare as different reference methods are often used. Other factors, such as protocols, quality control, type of blood (capillary vs. venous), populations, blood collection methods/techniques, geography/context, and equipment can also introduce challenges with comparison across studies. Where possible, results of systematic reviews and meta-analyses are presented in this landscape.
Portable hemoglobinometers

Portable hemoglobinometers are often used to estimate hemoglobin in field settings, as they are easily transported handheld devices that do not require access to refrigeration or electricity.\(^{21}\) Additionally, portable hemoglobinometers are advantageous in that they require only a small sample of capillary blood, provide instant quantitative results on a digital display, and are relatively inexpensive and simple to use, requiring only basic training. Portable hemoglobinometer technology functions based on the principles of colorimetry.

HemoCue® systems (HemoCue AB, Ängelholm, Sweden) are the most well-established portable hemoglobinometers and are considered the reference method for point-of-care testing.\(^{22}\) HemoCue released the HemoCue 201+ device in 1990, which was then followed by the HemoCue 301+.\(^{23}\) HemoCue devices use reagent-based absorption photometry to measure hemoglobin at dual wavelengths. Blood is collected via capillary draw into a microcuvette that is loaded into a reader, where it reacts with the reagents and hemoglobin is converted to hemoglobinazide.\(^{21,24}\) Errors in measurement can be introduced by improper cleaning of the device or improper blood-collection practices—particularly when using capillary samples.\(^{25}\) For example, using the incorrect blood volume or “milking the finger” during sample collection can influence the results.\(^{21,25}\) To address these issues, standardization protocols for blood-sample collection have been developed.\(^{26}\) Quality controls are also required and available from EuroTrol (Ede, The Netherlands).\(^{27}\)

A number of studies have compared HemoCue device performance to various reference tests. Of note, a recent systematic review found that HemoCue devices provide an unbiased, pooled estimate of laboratory hemoglobin.\(^{28}\) Although HemoCue devices have been shown to have high accuracy and precision in laboratory settings,\(^{29,30}\) greater variability is observed in field settings.\(^{21,25,31–34}\) Variability in performance has also been observed between different devices, models, and operators.\(^{35–39}\)

Apart from the HemoCue devices, a number of other portable hemoglobinometers have been developed and are commercially available, including the TrueHb (Wrig Nanosystems, New Delhi, India) and the URIT devices (URIT Medical Electronic Group Ltd., Guilin, China). A list can be found in table 3. However, the HemoCue devices are currently the only portable hemoglobinometers recommended by WHO.

Noninvasive approaches

Recent technological advancements have made noninvasive methods for point-of-care anemia screening a promising new option. A summary of noninvasive hemoglobin assessment devices and methods can be found in table 4. These methods do not require a blood sample to produce results, reducing the risk of infection and eliminating patient pain involved in testing. Noninvasive devices also have an inherently different cost structure than that of invasive methods, since they do not require additional material inputs for each test administered (e.g., microcuvettes). Instead of analyzing blood hemoglobin levels directly, noninvasive devices use spectrophotometry to estimate hemoglobin concentration based on light wavelength or photometry to estimate hemoglobin concentration based on light intensity. However, the methods used by these devices have not been recommended by WHO, and many are still in pilot or validation phases. Overall, there is a current lack of evidence supporting their diagnostic accuracy.
Pronto® and Radical® Devices

Multiple generations of the Pronto® and Radical® devices manufactured by Masimo Corporation (Irvine, California) use pulse CO-oximetry to monitor oxygen saturation in blood. These devices work by placing a sensor that measures different wavelengths of light onto the tip of a patient’s ring finger. Noninvasive and continuous hemoglobin SpHb® monitoring (Masimo Corp.) by more recent versions of these devices is made possible by Masimo rainbow® technology that can measure light at a broader spectrum of wavelengths. Current devices that use SpHb technology are Masimo’s Pronto Pulse and Radical-7® CO-Oximeters®. The Pronto Pulse CO-Oximeter is a spot-check monitor powered by four AA alkaline batteries that last for up to eight hours of use, and the Radical-7 is a continuous monitor that uses a rechargeable nickel-metal hydride battery with four hours of battery life and a three-hour charge time. The SpHb technology used by Masimo does not have the diagnostic power (accuracy, precision) of current WHO recommended methods for determining hemoglobin levels and, therefore, is not intended as a replacement for laboratory blood testing.28

NBM-200

Another method for noninvasive determination of hemoglobin is occlusion spectroscopy, as used by the NBM-200 device developed by OrSense (Petah Tikva, Israel). Similar to pulse CO-oximetry, occlusion spectroscopy relies on spectrophotometry to estimate hemoglobin concentration in the blood. However, the NBM-200 device places a ring-shaped probe around the finger and temporarily applies pressure to restrict blood flow, which creates an optical signal and results in a measurement. This approach does not require an adequate perfusion rate or pulse rate, unlike pulse CO-oximetry.40 The NBM-200 operates with four standard AA batteries or a built-in rechargeable lithium-ion backup battery.

Haemospect®

The Haemospect® device (MBR Optical systems, Wuppertal, Germany) uses transcutaneous reflection spectroscopy to measure hemoglobin levels. The Haemospect works by placing a sensor on the palm side of the dominant hand immediately below the index finger, and as subsequent measurements are often necessary to obtain a reading, a second measurement can be taken by placing the sensor on the forearm of the same arm.41 The sensor projects white light into the underlying tissue, and some of this light is absorbed while the rest is reflected back to the device to be broken down into separate wavelengths by a spectrometer and analyzed by an electronic evaluation unit connected to the system.42

HemaApp

HemaApp is an innovative smartphone application developed by electrical engineers and computer scientists at the University of Washington (Seattle, Washington) that measures hemoglobin levels through chromatic analysis by analyzing absorption properties of blood at different wavelengths of light.43 This technology draws from previously existing noninvasive methods using spectrophotometry to assess blood hemoglobin levels but leverages existing smartphone technology to offer a new and accessible strategy for implementation. Accuracy of this diagnostic can be improved by augmenting HemaApp with incandescent lights and infrared LED lights.43

ToucHb

ToucHb (Biosense, Irvine, California) is a unique noninvasive device in that it relies on reflectance photometry as opposed to spectrophotometry. Instead of analyzing different wavelengths of light, it
assesses overall light intensity as a way to quantitatively measure pallor and estimate hemoglobin concentration in the blood. This device captures an image of the patient’s exposed conjunctiva, which is then used to measure pallor and predict blood hemoglobin concentration in grams per deciliter.⁹
Table 1. Comparison of selected point-of-care anemia screening devices against the minimum target product profile (TPP) criteria.

Key
- **Meets criteria**
- **Partially meets criteria**
- **Does not meet criteria**
- **N/A** No information available

<table>
<thead>
<tr>
<th>TPP Criteria</th>
<th>Invasive</th>
<th>Noninvasive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Color Scales</td>
<td>Sahli’s method</td>
</tr>
<tr>
<td>Intended use/ use cases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>End user</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infrastructure level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical sensitivity and specificity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complexity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating temperature</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Sample collection and processing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target cost per result</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: PHMs, portable hemoglobinometers
Table 2. Summary of anemia screening methods based on manual visual comparison of blood samples.

<table>
<thead>
<tr>
<th>No.</th>
<th>Product or Method Name</th>
<th>Manufacturer (Location)</th>
<th>Web Link</th>
<th>Price (USD)</th>
<th>Sensitivity/ Specificity (95% Confidence Interval)</th>
<th>Peer-Reviewed References</th>
</tr>
</thead>
</table>
| 1   | WHO Colour Scale        | Copack GmbH (Oststeinbek, Germany) | [Link](#) | Approximately $10 for the basic kit (scale, instructions, and 200 test strips)\(^b\) | Estimates vary. According to a systematic review by Marn & Critchley (2016)\(^{10}\):
Pooled sensitivity: 80% (68%–88%)\(^{10}\)
Pooled specificity: 80% (59%–91%)\(^{10}\)
Pooled sensitivity (severe anemia): 57% (36%–76%)\(^{10}\)
Pooled specificity (severe anemia): 99.6% (95%–99.9%)\(^{10}\) | [10,44–60] |
| 2   | HCS-HLL                | Hindustan Lifecare Ltd. (Thiruvananthapuram, India) | No direct product link available. Manufacturer’s website: [Link](#) | N/A | Sensitivity (capillary sample, accuracy to screen): 92.0% (90.4%–93.3%)\(^9\)
Specificity (capillary sample, accuracy to screen): 21.9% (19.6%–24.2%)\(^9\)
Sensitivity (venous sample, accuracy to screen): 69.6% (67.1%–71.9%)\(^9\)
Specificity (venous sample, accuracy to screen): 59.5% (56.8%–62.2%)\(^9\)
Sensitivity (capillary sample, accuracy to screen for treating): 90.3% (88.2%–92.2%)\(^9\)
Specificity (capillary sample, accuracy to screen for treating): 42.2% (39.9%–44.5%)\(^9\)
Sensitivity (venous sample, accuracy to screen for treating): 67.1% (63.9%–70.2%)\(^9\)
Specificity (venous sample, accuracy to screen for treating): 72.8% (70.7%–74.8%)\(^9\) | [9] |

<table>
<thead>
<tr>
<th></th>
<th>Method</th>
<th>Manufacturers/Types</th>
<th>Example</th>
<th>Costs/Estimates/Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Sahli's method</td>
<td>Multiple manufacturers of Sahli's hemoglobinometers</td>
<td>Example: <a href="https://www.indiamart.com/proddetail/sahli-type-haemoglobin-meter-15672891530.html">Link</a></td>
<td>Approx. $11 for the Sahli hemoglobinometer. Additional supplies are also required.</td>
</tr>
<tr>
<td>4</td>
<td>Microhematocrit readers</td>
<td>Multiple reader types and manufactures</td>
<td>Example: <a href="https://www.grainger.com/product/54PC09?cm_mmc=PPC:+Google+PLA&amp;s_kwcid=AL!2966!3!50916768717!!!g!111150354597!&amp;ef_id=Wn5DAwAAAQL.I7tlm.20180619171605:s">Link</a></td>
<td>Varies depending upon reader type. Some readers range from $25–$75 (^{d,e})</td>
</tr>
</tbody>
</table>

\(^{c}\) Source: [https://www.indiamart.com/proddetail/sahli-type-haemoglobin-meter-15672891530.html](https://www.indiamart.com/proddetail/sahli-type-haemoglobin-meter-15672891530.html)

\(^{d}\) Source: [https://www.grainger.com/product/54PC09?cm_mmc=PPC:+Google+PLA&s_kwcid=AL!2966!3!50916768717!!!g!111150354597!&ef_id=Wn5DAwAAAQL.I7tlm.20180619171605:s](https://www.grainger.com/product/54PC09?cm_mmc=PPC:+Google+PLA&s_kwcid=AL!2966!3!50916768717!!!g!111150354597!&ef_id=Wn5DAwAAAQL.I7tlm.20180619171605:s)

\(^{e}\) Source: [https://mfimedical.com/products/unico-microhematocrit-reader?variant=19995835011&gclid=CjwKCAjw06LZ8RBNEiwA2vgMVaQyY46k4CN9isTAdyMdQTzFAz-vLdBY30eY2LDzeSYGz2zg8BeCZ7wQAvD_BwE](https://mfimedical.com/products/unico-microhematocrit-reader?variant=19995835011&gclid=CjwKCAjw06LZ8RBNEiwA2vgMVaQyY46k4CN9isTAdyMdQTzFAz-vLdBY30eY2LDzeSYGz2zg8BeCZ7wQAvD_BwE)
Table 3. Summary of portable hemoglobinometers.

<table>
<thead>
<tr>
<th>No.</th>
<th>Product Name</th>
<th>Manufacturer (Location)</th>
<th>Web Link</th>
<th>Price (USD)</th>
<th>Sensitivity/ Specificity (95% Confidence Interval)</th>
<th>Peer-Reviewed References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HemoCue® Hb 201+</td>
<td>HemoCue AB (Angelholm, Sweden)</td>
<td><a href="#">Link</a></td>
<td>Approximately $320¹</td>
<td>Estimates vary. Only a selection are presented herein. Sensitivity (≤11 g/dl): 85% (79%–90%)[48,61] Specificity (≤11 g/dl): 80% (76%–83%)[48,61] Sensitivity (capillary blood, adults ≥17 years): 79%²⁵ Specificity (capillary blood, adults ≥17 years): 97%²⁵ Sensitivity (venous blood, adults ≥17 years): 86%²⁵ Specificity (venous blood, adults ≥17 years): 97%²⁵ Sensitivity (capillary blood, children 0.5–15 years): 84%²⁵ Specificity (capillary blood, children 0.5–15 years): 93%²⁵ Sensitivity (venous blood, children 0.5–15 years): 87%²⁵ Specificity (venous blood, children 0.5–15 years): 93%²⁵ Sensitivity: 70.6%³⁴ Specificity: 95.2%³⁴</td>
<td>[21, 25, 28–32, 34, 48, 61]</td>
</tr>
<tr>
<td>2</td>
<td>HemoCue® 301+</td>
<td>HemoCue AB (Angelholm, Sweden)</td>
<td><a href="#">Link</a></td>
<td>HemoCue Hb 301 Analyzer price: 100 units = US$527.30 per unit = Total cost US$52,730</td>
<td>Estimates vary. Only a selection are presented herein. Sensitivity (females, 12 g/dl cutoff): 72%⁶⁵ Specificity (females, 12 g/dl cutoff): 70%⁶⁵ Sensitivity (males, 13 g/dl cutoff): 50%⁶⁵ Specificity (males, 13 g/dl cutoff): 70%⁶⁵</td>
<td>[35–37, 39, 65]</td>
</tr>
</tbody>
</table>

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>DiaSpect Tm</td>
<td>EKF Diagnostics (Cardiff, United Kingdom)</td>
<td>Link</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (females and males, respective cutoffs): 70%&lt;sup&gt;66&lt;/sup&gt; Specificity (females and males, respective cutoffs): 70%&lt;sup&gt;65&lt;/sup&gt; Sensitivity: 61.9%&lt;sup&gt;37&lt;/sup&gt; Specificity: 100%&lt;sup&gt;37&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[66]</td>
</tr>
<tr>
<td>4</td>
<td>HemoPoint® H2</td>
<td>EKF Diagnostics (Cardiff, United Kingdom)</td>
<td>Link</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>HemoPoint H2 Analyzer: 100 units = US$600 per unit = Total cost US$60,000 500 units = US$600 per unit = Total cost US$300,000 1,000 units = US$500 per unit = Total cost US$500,000 HemoPoint H2 Microcuvettes: 2x50 cuvettes = US$86 4x50 cuvettes = US$165</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>

<sup>a</sup> Source: Manufacturer price quote (Ex Works) for Ethiopia.

<sup>b</sup> Source: Manufacturer price quote (Ex Works) for Ethiopia.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>True Hb™</td>
<td>Wrig Nanosystems (New Delhi, India)</td>
<td>Link</td>
<td>82.1% (79.8%–84.2%)</td>
<td>77.9% (75.3%–80.3%)</td>
<td>74.4% (71.9%–76.8%)</td>
<td>86.9% (84.8%–88.8%)</td>
<td>79.4% (76.4%–82.1%)</td>
<td>87.1% (85.3%–88.7%)</td>
<td>70.7% (67.4%–73.9%)</td>
<td>87.9% (92.5%–94.9%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>HemoControl</td>
<td>EKF Diagnostics (Cardiff, United Kingdom)</td>
<td>Link</td>
<td>100 units = €475 per unit</td>
<td>Estimates vary.</td>
<td>Sensitivity: 86.8%</td>
<td>Specificity: 94.7%</td>
<td>Sensitivity: 83.3%</td>
<td>Specificity: 87.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>500 units = €410 per unit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,000 units = €345 per unit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Anemia and Malnutrition Device</td>
<td>Path Shodh (Bangalore, India)</td>
<td>Link</td>
<td>Contact manufacturer</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

1 Source: Manufacturer price quote (Ex Works) for Ethiopia.
2 Source: Manufacturer price quote (Ex Works) for Ethiopia.
3 No response received from manufacturer.
<table>
<thead>
<tr>
<th>#</th>
<th>Product</th>
<th>Manufacturer</th>
<th>Link</th>
<th>Price and Details</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>i-STAT® System</td>
<td>Abbott (Princeton, NJ)</td>
<td>Link</td>
<td>i-STAT 1 Analyzer including Downloader, Printer, and Electronic Simulator: US$7,000 EGC+ Cartridge (Bx/25)—sodium, potassium, hemoglobin, hematocrit, pH, PCO2, PO2, TCO2, HCO3, BE, sO2: US$135&lt;sup&gt;1&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>9</td>
<td>QDx Hemostat</td>
<td>DiaSys Diagnostic Systems GmbH (Holzheim, Germany)</td>
<td>Link</td>
<td>Contact manufacturer&lt;sup&gt;m&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>10</td>
<td>AccuQuik™ Hemoglobin System</td>
<td>AccuQuik Test Systems (Wilmington, DE)</td>
<td>Link</td>
<td>Contact manufacturer&lt;sup&gt;n&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>11</td>
<td>CompoLab TM</td>
<td>Fresnius Kabi India Pvt. Ltd. (Pune, India)</td>
<td>Link</td>
<td>Contact manufacturer&lt;sup&gt;o&lt;/sup&gt;</td>
<td>[42,70,71]</td>
</tr>
<tr>
<td>12</td>
<td>CompoLab TS</td>
<td>Fresnius Kabi India Pvt. Ltd. (Pune, India)</td>
<td>Link</td>
<td>Contact manufacturer&lt;sup&gt;p&lt;/sup&gt;</td>
<td>[42,70,71]</td>
</tr>
<tr>
<td>13</td>
<td>URIT-12</td>
<td>URIT Medical Electronic Group Ltd. (Guilin, China)</td>
<td>Link</td>
<td>URIT-12 Hemoglobin Meter: US$80 for 100 units; US$75 for 500 units; US$68 for 1,000 units URIT H12 Hemoglobin test (25 strips per bottle): US$10</td>
<td>Community-based, clinical setting: Sensitivity (females; 12 g/dl cutoff): 100%&lt;sup&gt;65&lt;/sup&gt; Specificity (females; 12 g/dl cutoff): 7%&lt;sup&gt;65&lt;/sup&gt; Sensitivity (males,13 g/dl cutoff): 100%&lt;sup&gt;65&lt;/sup&gt; Specificity (males,13 g/dl cutoff): 6%&lt;sup&gt;65&lt;/sup&gt; Sensitivity (males and females, with respective cutoffs): 100%&lt;sup&gt;65&lt;/sup&gt; Specificity (males and females, with respective cutoffs): 7%&lt;sup&gt;65&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>1</sup> Source: Manufacturer price quote for Ethiopia. Additional six percent freight for cartridges and four percent freight for instrument for Cargo Insurance Paid (CIP) shipping terms.

<sup>m</sup> No response received from manufacturer.

<sup>n</sup> No quote received from manufacturer.

<sup>o</sup> No response received from manufacturer.

<sup>p</sup> No response received from manufacturer.
<table>
<thead>
<tr>
<th></th>
<th>Item</th>
<th>Supplier/Manufacturer</th>
<th>Reference</th>
<th>Price/Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>URIT-15</td>
<td>URIT Medical Electronic Group Ltd.</td>
<td>Link</td>
<td>Only available in domestic market. Not available in international market until late 2018.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Guilin, China)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Hemosmart Gold</td>
<td>ApexBio</td>
<td>Link</td>
<td>Price negotiable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Hsinchu City, Taiwan)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Hemachroma Plus</td>
<td>Boditech Med Inc.</td>
<td>Link</td>
<td>Contact manufacturer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Chungcheon-si, South Korea)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Benecheck HB</td>
<td>General Life Biotechnology</td>
<td>Link</td>
<td>Contact manufacturer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(New Taipei City, Taiwan)</td>
<td>N/A</td>
<td>[73]</td>
</tr>
<tr>
<td>18</td>
<td>CERA-CHEK™ HB plus</td>
<td>GCMedis</td>
<td>Link</td>
<td>Contact manufacturer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Cheonan, South Korea)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>HG-220</td>
<td>APEL Co. Ltd.</td>
<td>Link</td>
<td>Approx. $1,800–$2,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Kawaguchi, Japan)</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

---

* Source: Manufacturer price quote (Ex Works) for Ethiopia.
* Source: Manufacturer correspondence.
* Source: Manufacturer correspondence.
* No response received from manufacturer.
* No response received from manufacturer.
* No response received from manufacturer.
<table>
<thead>
<tr>
<th>No.</th>
<th>Product or Approach Name</th>
<th>Manufacturer (Location)</th>
<th>Web Link</th>
<th>Price</th>
<th>Sensitivity/ Specificity (95% Confidence Interval)</th>
<th>Peer-Reviewed References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Haemospect® MBR Optical Systems (Wuppertal, Germany)</td>
<td>Link</td>
<td>US$500(^x)</td>
<td>Estimates vary.</td>
<td>Sensitivity: 66.7%(^{68}) Specificity: 77.1%(^{68})</td>
<td>[41,42,68,70,74]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (men): 3.5%(^{74}) Specificity (men): 95.9%(^{74})</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (women): 10.8%(^{74}) Specificity (women): 95.0%(^{74})</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Pronto® Pulse CO-Oximeter® Masimo Corp (Irvine, California, USA)</td>
<td>Link</td>
<td>$522(^y) – $699(^z)</td>
<td>Estimates vary.</td>
<td>Sensitivity: 82% (75–90%)(^{75}) Specificity: 65% (56%–74%)(^{75})</td>
<td>[28,75–96]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (DCI mini): 66–72%(^{76}) Specificity (DCI mini): 70–84%(^{76})</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (men): 93%(^{77}) Specificity (women): 75%(^{77})</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (men): 77%(^{77}) Specificity (women): 81%(^{77})</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity: 95.4%(^{78}) Specificity: 63.8%(^{78})</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity: 93%(^{79}) Specificity: 83%(^{79})</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Radical-7® Masimo Corp (Irvine, California, USA)</td>
<td>Link</td>
<td>$1,295(^aa) – $2,795(^bb)</td>
<td>Estimates vary.</td>
<td>Sensitivity: 61% (32%–86%)(^{123}) Specificity: 85% (55%–98%)(^{123})</td>
<td>[28,82,97–125]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (MetHb): 92.6–100%(^{124})</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^x\) Source: https://www.frontierhealth.co/products/haemospect-hemoglobin-device.
<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>NBM-200</td>
<td>Orsense (Petah-Tikva, Israel)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
|   |   |   |   | Specificity (MetHb): 92.4–100.0%[^124]  
Sensitivity: 79%[^125]  
Estimates vary. |
|   |   |   |   | Sensitivity: 70.59% (52.52%–84.90%)[^126]  
Specificity: 98.93% (97.51%–99.65%)[^126]  
Sensitivity (Men): 12.1%[^74]  
Specificity (Men): 98.6%[^74]  
Sensitivity (Women): 17.0%[^74]  
Specificity (Women): 94.6%[^74]
|   |   |   |   | Sensitivity: 71.7%[^66]  
Specificity: 79.5%[^66]  
Sensitivity (Men, Hb<13.5 g/dL): 14.47%[^127]  
Specificity (Men, Hb<13.5 g/dL): 98.89%[^127]  
Sensitivity (Women, Hb<12.5 g/dL): 32.34%[^127]  
Specificity (Women, Hb<12.5 g/dL): 95.12%[^127]  
Sensitivity: 38.6% (28.1–50.3%)[^40]  
Specificity: 93.6% (90.9–95.5%)[^40]  
Sensitivity: 98%[^79]  
Specificity: 97%[^79] |
| 5 | TouchHb | Biosense (Irvine, CA) |   |   |
|   |   |   |   | Sensitivity (accuracy to screen patients with anemia): 73.1% (70.7%–75.4%)[^9]  
Specificity (accuracy to screen patients with anemia): 51.5% (48.7%–54.3%)[^9]  
Sensitivity (accuracy to screen patients for treating anemia): 44.3% (41.7%–47.0%)[^9]  
Specificity (accuracy to screen patients for treating anemia): 80.5% (78.2%–82.7%)[^9] |
|   |   |   |   | Contact manufacturer[^d4] |

[^d4] Source: [http://innovations.bmj.com/content/bmjinnov/early/2016/08/10/bmjinnov-2016-000139.full.pdf](http://innovations.bmj.com/content/bmjinnov/early/2016/08/10/bmjinnov-2016-000139.full.pdf)  
[^d4] No response received from manufacturer.
<table>
<thead>
<tr>
<th></th>
<th>Product Name</th>
<th>University/Location</th>
<th>Link</th>
<th>N/A</th>
<th>Sensitivity (smartphone LEDs): 78.6%43</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Specificity (Smartphone LEDs): 70.6%43</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (incandescent light): 85.7%43</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Specificity (incandescent light): 70.6%43</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (incandescent light &amp; custom LED): 85.7%43</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Specificity (incandescent light &amp; custom LED): 76.5%43</td>
</tr>
<tr>
<td>6</td>
<td>HemaApp</td>
<td>University of Washington (Seattle, WA)</td>
<td>Link</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Hb Meter App</td>
<td>N/A</td>
<td>Link</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>8</td>
<td>Quantifying conjunctival pallor using digital photographs</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Sensitivity (iPhone 5s camera): 74% (52–90%)130</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Specificity (iPhone 5s camera): 71% (49–87%)130</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitivity (Panasonic DMC-LX5 digital camera): 57% (34–77%)130</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Specificity (Panasonic DMC-LX5 digital camera): 83% (63–95%)130</td>
</tr>
<tr>
<td>9</td>
<td>Measuring red blood cell zinc protoporphyrin in the microcirculation of the lower lip using optical fiber probes</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Sensitivity: 97% (87–100%)131</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Specificity: 90% (73–98%)131</td>
</tr>
</tbody>
</table>
References


