

## **Request for Bid**

### **Blood Monitoring Device for Patients Prescribed Clozapine**

#### **1. Introduction and Purpose**

The Iowa Department of Health and Human Services (Agency) is seeking bids for a medical device capable of accurately measuring White Blood Cells (WBCs) and Absolute Neutrophil % (ANC) levels to support healthcare professions at the Cherokee Mental Health Institute (CMHI) in monitoring patients undergoing treatment with Clozapine. The device must be able to provide reliable, precise, and real time results.

#### **2. Device Specifications and Requirements**

This device should meet, at a minimum, the following requirements:

- a. Capable of measuring White Blood Cells (WBCs) and Absolute Neutrophil % (ANC) levels and providing quantitative results from capillary blood retrieved through a fingerstick.
- b. Fast and efficient testing with a target turnaround time of results not exceeding twenty (20) minutes.
- c. Test results available on-site without outsourcing to a laboratory for processing.
- d. Blood sample used to produce test result is capillary blood obtained through a fingerstick in lieu of venous blood draw.
- e. Clear and legible digital results available either on device or accompanying software.
- f. Compact design suitable for use in clinical environments, such as hospitals, clinics, or physicians' offices.
- g. FDA-approved or equivalent regulatory certification for medical use.

#### **3. Software and Data Management and Security Requirements**

1. The Service Provider shall comply with either of the following:
  - a. Provide certification of compliance with a minimum of one of the following security frameworks, if the Contractor is storing Confidential Information electronically: NIST SP 800-53, HITRUST version 9, SOC 2, COBIT 5, CSA STAR Level 2 or greater, ISO 27001 or PCI-DSS version 3.2 prior to implementation of the system and again when the certification(s) expire, or
  - b. Provide attestation of a passed information security risk assessment, passed network penetration scans, and passed web application scans (when applicable) prior to implementation of the system and again annually thereafter. For purposes of this section, "passed" means no unresolved high or critical findings.

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Kelly Garcia, Director

2. If using cloud services to store Agency Information, the Service Provider shall comply with either of the following:
  - a. Provide written designation of FedRAMP authorization with impact level moderate prior to implementation of the system, or
  - b. Provide certification of compliance with a minimum of one of the following security frameworks: HITRUST version 9, SOC 2, COBIT 5, CSA STAR Level 2 or greater or PCI-DSS version 3.2 prior to implementation of the system and again when the certification(s) expire.
3. Device software should have the capability to generate patient reports, track historical data, and alert for abnormal blood levels.
4. If applicable, the selected vendor must be agreeable to a Business Associate Agreement with the State of Iowa. Additional information on this agreement is available at <https://hhs.iowa.gov/hipaa>.

#### 4. Bid Submission Instructions

The Agency intends to award this Request for Bid to the bidder that meets all minimum criteria as outlined in this solicitation at the lowest proposed cost. Please include the following elements, if applicable, in your proposal:

- a. Cost of device;
- b. Cost of any additional supplies required on a routine basis for functionality such as test strips, etc.;
- c. Cost of software if not included in the purchase of the device;
- d. If the device requires ongoing support, please provide details including what support is provided and what the ongoing cost is;
- e. If the device has a warranty, please provide details of what the warranty includes and length of time it is applicable.

#### 5. Timetable

The dates set forth below are for informational purposes only. The Agency reserves the right to change these dates:

5/5/2025	Submit Request for Bid to Targeted Small Business web page.
5/7/2025	Submit Request for Bid to Bid Opportunities website for public notification.
5/16/2025	Proposals are due.
5/20/2025	Send Notice of Intent to Award naming apparent successful Bidder.

#### 6. Terms and Conditions

The State of Iowa Standard Terms and Conditions are found at <https://das.iowa.gov/vendor-resources/procurement-terms-and-conditions>

#### 7. Deadline and Submission Information

Please submit proposal by email to [CHEMHIPurchasing@hhs.iowa.gov](mailto:CHEMHIPurchasing@hhs.iowa.gov) no later than 2:00 PM central time on May 16, 2025.

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For questions regarding this solicitation, please contact:

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