

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0648454	(X3) Date Survey Completed 04/14/2023
Name of Provider or Supplier Hazelwood Center	Street Address, City, State 1800 Old Bluegrass Ave, Louisville, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was conducted on 04/14/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493 with Condition level deficiencies cited. The Condition at 42 CFR 493.1409, laboratories performing moderate complexity testing; technical consultant was not met and additional standard level deficiencies were cited.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing documents and interview with Testing Personnel (TP) #2, the laboratory director and the testing personnel failed to sign the proficiency testing attestation statement for 1 out of 6 proficiency test events reviewed. The findings include: Review of the "2023 Hematology/Coagulation 1st Event Attestation Statement" revealed the statement was not signed by the laboratory director or the person(s) that performed the test. The document specified, "Signatures Required - For all PT [proficiency testing] results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." In an interview on 04/14/2023 at 10:10 AM, Testing Personnel (TP) #2 stated she performed the proficiency testing for the hematology event of 2023 and acknowledged the attestation form was not signed by her or the laboratory director.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of the CMS-209, the laboratory's Quality Assurance Plan, competency assessment records and interview with the staff, the laboratory failed to perform and document annual competency for two (2) of two (2) testing personnel. The findings include: 1. Review of the "Laboratory Personnel Report (CLIA) [Clinical Laboratory Improvements]," signed by the Laboratory Director and dated 04/11/2023, revealed two (2) employees held the position of TP. 2. Review of the laboratory "Quality Assurance Plan," specified, "New personnel are evaluated for competency twice for the first year and yearly thereafter." 3. Review of TP #1's "Competency Assessment Record," revealed no competency records for 2022. Review of TP #2's "Competency Assessment Record," revealed no competency records for 2021 and 2022. 4. In an interview on 04/14/2023 at 10:40 AM, TP #1 and TP #2 acknowledged their competencies had not been done due to the retirement of the technical consultant.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid (CMS) 209 form and CMS 116 form, review of personnel records, and interview with Testing Person (TP) #1, the laboratory failed to have a qualified technical consultant for four (4) of four (4) months (January to April 14, 2023). Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of

laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's application, personnel report and interview, it was determined the laboratory, which performed moderately complexity testing, failed to have a qualified technical consultant (TC) for four (4) of four (4) months (January to April 14, 2023). The findings include: 1. Review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification CMS-116," signed by the laboratory director (LD) and dated 04/11/2023, indicated the laboratory performed complete blood count (CBC) tests, a moderate complexity test. 2. Review of the "Laboratory Personnel Report (CLIA) CMS-209," signed by the LD and dated 04/11/2023, revealed no employee held the position of TC. In an interview on 04/14/2023 at 10:30 AM, Testing Personnel (TP) #1 stated the TC retired in December 2022 and no one currently held the position of TC. 3. An interview at 12:10PM on 04/14/2023 with the Laboratory Director (LD) confirmed the findings.