

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2271228	(X3) Date Survey Completed 09/10/2024
Name of Provider or Supplier Hoskinson Health & Wellness Clinic	Street Address, City, State 469 Wy-50, Gillette, WY	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing documentation and staff interview, the laboratory failed to enroll in an approved proficiency testing program for the regulated manual identification of blood cells for 2 of 2 years (2023, 2024) reviewed. The laboratory performed approximately 100 manual blood cell identifications on patient samples per year. The findings were: 1. Review of the 2023 Event #2 through the 2024 Event #2 Wisconsin State Laboratory of Hygiene proficiency testing records showed the laboratory was enrolled in an automated complete blood count with a white blood cell differential program; however, had failed to enroll in a program to evaluate the manual method for identifying blood cells. 2. Interview with the technical supervisor on 9/10/24 at 2 PM confirmed the laboratory had failed to enroll in a proficiency testing program for manually identifying blood cells.</p>
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</p>

laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records and staff interview, the laboratory director failed to attest to the routine integration of the WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing events into the patient workload using the laboratory's routine methods for 3 of 17 proficiency testing events reviewed from June 2023 through August 2024. The findings were: 1. Review of the 2023 WSLH Coagulation event #2, the 2023 WSLH Hematology event #2, and the 2024 WSLH Bacteriology-Viral event #2 records showed the laboratory director had failed to sign the attestation statements. 2. Interview with the technical supervisor on 9/10/24 at 10:01 AM confirmed no further documentation was available.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel records, policy and procedure review, and staff interview, the laboratory failed to ensure the 6-month competency assessment was completed for 2 of 3 (TP #1, TP #2) testing personnel; and a policy and procedure was developed for assessing the competency of the general and technical supervisors. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report showed the laboratory employed one technical supervisor, one general supervisor, and three testing personnel. The following concerns were identified: a. Review of the personnel file for TP #1 showed she was hired in January of 2024. There was no evidence a 6-month competency assessment had been completed. b. Review of the personnel file for TP #2 showed she was hired on 8/23/23. There was no evidence a 6-month competency assessment had been completed. c. Review of the personnel files for the general supervisor and technical supervisor showed no competency assessments had been completed for the responsibilities of either position. 2. Review of the Quality Assurance Plan policy, approved by the laboratory director on 4/8/24, showed "... PERSONNEL ASSESSMENT Twice a year the first year and at least annually thereafter, the Technical Consultant [the lab was previously a moderate complexity laboratory] will review performance of each employee working in the laboratory to assure employee competency. This will be accomplished by having each employee perform split sample testing, by direct observation of testing skills, and by continuing education seminars. The written results of the review will be filed in the individual's personnel file." Further review of the policy showed no evidence a procedure had been developed to ensure the competency of the general and technical supervisor's responsibilities. 3. Interview with the technical supervisor on 9/10/24 at 10:24 AM confirmed the 6-month competency assessments had not been completed and a procedure had not been developed to assess the competency of the technical and general supervisors.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records, lack of documentation, policy and procedure review, and staff interview, the laboratory failed to have a system in place for reviewing proficiency test results that received an artificial score of 100% for 3 of 17 WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing events reviewed from June 2023 through August 2024. The findings were: 1. Review of the WSLH 2024 Hematology Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on the reticulocyte count challenge due to an insufficient peer group. There was no documentation a self-evaluation of the reticulocyte count results had been completed. 2. Review of the WSLH 2024 Special Chemistry Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on the analyte of estradiol. Sample CS-03 was not graded to a lack of consensus. There was no documentation a self-evaluation of the estradiol result had been completed. 3. Review of the WSLH 2024 Bacti-Viral Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on the detection of norovirus. Sample EP-5 was not graded to a lack of consensus. There was no documentation a self-evaluation of the norovirus result had been completed. 4. Interview with the technical supervisor on 9/10/24 at 10:01 AM confirmed no further documentation was available. 5. Review of the Proficiency Testing Corrective Action procedure showed "Non-graded Proficiency Testing Results All results labeled as not-graded by the Proficiency Testing Agency will be self-graded and evaluated by the laboratory staff and Technical Consultant [the laboratory was previously a moderate complexity laboratory]. The laboratory will print all statistical data available from the proficiency agency in reference to each non-graded analyte or result. The laboratory will evaluate their participation in comparison to the other participants based on the results reported."

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the CMS (Centers for Medicare and Medicaid Services)-116 form, procedure manual review, and staff interview, the current laboratory director failed to sign and date as approved 1 of 7 policies and procedures (BioFire gastrointestinal panel) reviewed. The findings were: 1. Review of the CMS-116 form showed a change of the laboratory director, effective 4/1/24, was approved on 4/3/24. 2. Random review of the laboratory's procedure manual showed 1 out of 7 policies and procedures had not been signed by the current laboratory director. 3. Interview with the technical supervisor on 9/10/24 at 1:21 PM confirmed the procedure had not been signed as approved by the current laboratory director.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on new instrument and new test method verification study review, lack of documentation, and staff interview, the laboratory failed to ensure the verification studies were complete for 4 of 10 (Beckman Coulter-Scopio, Beckman Coulter Dxl 600, Beckman Coulter DxC 700 AU, ACL Top 350 CTS) verification studies reviewed. The findings were: 1. Review of the Beckman Coulter-Scopio new instrument verification study used for the identification of blood cells showed data had been collected; however, an evaluation of the data which included precision and accuracy had not been conducted. Interview with the technical supervisor on 9/10/24 at 1:49 PM revealed the laboratory had started using the instrument for patient testing in January of 2024. 2. Review of the Beckman Coulter Dxl 600 verification study showed data was collected to verify accuracy; however, an evaluation of the data had not been conducted. In addition, the laboratory failed to confirm the manufacturer's normal values were appropriate for the laboratory's patient population. 3. Review of the Beckman Coulter DxC 700 AU verification study showed data was collected to verify accuracy however, an evaluation of the data had not been conducted. In addition, the laboratory failed to confirm the manufacturer's reference ranges were appropriate for the laboratory's patient population. 4. Review of the ACL Top 350 CTS coagulation analyzer verification study showed the laboratory failed to confirm the manufacturer's reference ranges were appropriate for the laboratory's patient population. 5. Interview with the technical supervisor on 9/10/24 at 1:49 PM confirmed no further documentation was available.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on review of new instrumentation and/or new test method verification records and staff interview, the laboratory director failed to evaluate and approve the results of the verification study for 4 of 10 (BioFire gastrointestinal panel, BioFire respiratory panel, Cepheid CoV-2/ Flu/RSV panel, Beckman Coulter-Scopio) new instrument and /or new test verification studies reviewed. The findings were: 1. Review of the BioFire gastrointestinal panel verification study showed it was signed as completed by TP (testing personnel) #2 on 1/18/24; however, there was no evidence the laboratory director had reviewed and approved the verification study prior to patient testing. 2. Review of the BioFire respiratory panel verification study showed it was signed as

completed by TP #2 on 1/8/24; however, there was no evidence the laboratory director had reviewed and approved the verification study prior to patient testing. 3. Review of the Cepheid XpertXpress CoV-2/Flu/RSV panel verification study showed it was signed by the technical supervisor on 10/23/23; however, there was no evidence the laboratory director had reviewed and approved the verification study prior to patient testing. 4. Review of the Beckman Coulter-Scopio new instrument verification study used for the identification of blood cells showed data had been collected; however, an evaluation of the data which included precision and accuracy had not been conducted. Interview with the technical supervisor on 9/10/24 at 1:49 PM revealed the laboratory had started using the instrument for patient testing in January of 2024. There was no evidence the laboratory director had reviewed and approved the verification study prior to patient testing. 5. Interview with the technical supervisor on 9/10/24 at 11:40 AM confirmed the laboratory director had not signed and approved the verification studies prior to patient testing.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on policy and procedure review and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties of the general and technical supervisors. The findings were: 1. Review of the laboratory's policies and procedures showed no documentation of what responsibilities had been delegated to the general supervisor or the technical supervisor. 2. Interview with the technical supervisor on 9/10/24 at 10:24 AM confirmed no documentation was available that defined the responsibilities of the general supervisor and the technical supervisor.