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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>25D1107381 | <b>(X3) Date Survey Completed</b><br><br>06/19/2024 |
| <b>Name of Provider or Supplier</b><br><br>Avalon Medical Clinic Llc   | <b>Street Address, City, State</b><br><br>1413 W Quitman Street, Iuka, MS  |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D2000</b>              | <p>ENROLLMENT AND TESTING OF SAMPLES<br/>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:<br/>Based on review of the Centers for Medicare and Medicaid Services (CMS) database system for proficiency testing CASPER report 0155D, laboratory records, and interview with testing personnel (TP#1)/Office Manager, the laboratory failed to enroll and participate in an HHS approved proficiency testing (PT) program for Hematology-CBC (Complete Blood Count) for two of two proficiency testing events for 2024. Findings Include: 1. Review of the CMS CASPER report for proficiency testing for the laboratory did not generate a report for any proficiency testing scores for 2024. 2. Review of laboratory records confirmed there was no documentation of enrollment or participation in an HHS approved proficiency testing program for Hematology for 2024. 3. The TP#1/Office Manager confirmed on 6/19/2024 at 2:00 p. m. that the laboratory was not enrolled in proficiency testing for CBC testing for two of two proficiency events in 2024.</p> |
| <b>D5209</b>              | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES<br/>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 review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel records and interview with testing personnel (TP) #1/Office Manager, the laboratory failed to establish and follow written policies to assess the technical consultant (TC) for one of one annual competencies. Findings include: 1. Review of the personnel records along with the 209 personnel form, revealed there was no annual competency/evaluation available for review. 2. Interview with the TP #1/Office Manager, confirmed on 6/19/2024 at 4:30 p.m. the technical consultant's competency had not been performed by the laboratory director since the TC was hired in December 2022.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing records, Centers for Medicare and Medicaid Services (CMS) database proficiency testing CASPER report 0155D and confirmation with testing personnel (TP)#1/Office Manager, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program for CBC (complete blood count) performed on the Sysmex XP 300 hematology analyzer for four of six testing events the year 2024. Findings include: 1. Review of the CMS database proficiency testing CASPER report revealed no scores or participation for CBC for the 1st and 2nd events of 2024. 2. Review of the laboratory proficiency records from 10/12/2022 through 6/19/2024, revealed no evidence of proficiency testing enrollment or participation for the 1st or 2nd events of 2024. 3. The TP#1/Office Manager confirmed in an interview on 6/19/2024 at 2:00 p.m. that the laboratory director did not ensure the laboratory was enrolled in proficiency testing for CBC for the the year 2024.

**D6041**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing records, Centers of Medicare and Medicaid Services (CMS)testing report and interview with testing personnel (TP) #1/Office Manager, the technical consultant failed to ensure the laboratory enrolled

and participated in an HHS approved proficiency testing (PT) program for CBC (complete blood count) performed on the Sysmex XP 300 hematology analyzer for the 2nd and 3rd events of 2023 and enroll in 2024. Findings include: 1. Review of the laboratory proficiency records for 2022, 2023 and 2024, and the CMS database report revealed no proficiency testing was reported and the laboratory did not perform or participate in proficiency testing for CBC's for the 2nd and 3rd events of 2023 nor did the laboratory enroll and participate in the 1st and 2nd events of 2024. The laboratory did not participate in 4 of 6 proficiency events since the last survey 10/12/2022. 2. The TP#1/Office Manager confirmed in an interview on 6/19/2024 at 10:00 a.m that the laboratory did not participate in the 2nd and 3rd proficiency events of 2023 and 1st and 2nd events of 2024 for hematology testing (CBC). The laboratory was still performing and reporting patient CBC testing during this timeframe.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:  
Based on review of laboratory testing records, policy and procedure manual and interview with the testing personnel (TP)#1/Office Manager, the technical consultant (TC) failed to document review of the Sysmex XP 300 calibration, quality controls, maintenance and temperature logs for 8 of 20 months. Findings Include: 1. Review of the laboratory policy and procedure manual revealed the Technical Consultant would visit the laboratory a minimum of quarterly per year. During those visits he/she would: a. Print and review the CBC daily quality control b. Review the maintenance logs the CBC instrument c. Review temperatures logs for room, refrigerator and freezer d. Review proficiency testing results e. Perform other technical consultant responsibilities as need. These duties/responsibilities had not been performed by the TC since 10/10/23 2. Review of laboratory records from 10/12/2022 through 6/19 /2024 revealed no documented review by the TC for the following records : a. Laboratory temperature logs (room, refrigerator, freezer, humidity). (8 of 20 months) b. Sysmex XP 300 calibration on 11/2/23 c. Sysmex XP 300 quality controls. (8 of 20 months) d. Sysmex XP 300 maintenance (daily, weekly, monthly, quarterly). (8 of 20 months) 3. Interview with TP #1/Office Manager on 6/19/2024 at 4:30 p.m. confirmed there was no available documentation of review of these records by the technical consultant after 10/10/2023.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel (TP) records including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel competency evaluations, and interview with TP#1/Office Manager, the technical consultant failed

to evaluate the performance for testing personnel, (TP) #1 listed on the CMS 209 form, at least annually for the year 2023. Findings include: 1. The surveyor reviewed personnel records from 10/12/2022 through 6/19/2024 including competency evaluations and the CMS 209 personnel form. 2. There was no annual competency evaluation for TP#1 performed by the TC for 2023. 3. The initial training for TP#1 was completed on 12/6/2022. The 6 month evaluation was performed on 7/14/2023 and the first annual competency was due in 12/2023. 4. The TP#1/Office Manager confirmed in an interview on 6/19/2024 at 4:30 p.m. that no annual competency evaluation had been documented as performed by the TC for TP#1. (1 of 1 annual competency evaluation was not performed).