

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0939915	(X3) Date Survey Completed 03/19/2025
Name of Provider or Supplier Jackson Clinic, Pa Of Huntingdon,The	Street Address, City, State 20719 East Main Street, Huntingdon, TN	
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
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 and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), the laboratory procedure manual, lack of documentation, review of maintenance records, and staff interview, the laboratory failed to follow its' testing personnel policy for training and competency assessments for one of one new testing persons for the use of the Sysmex XP 300 Complete Blood Count with automated white blood cell differential (CBC w /Diff) instrument. The findings include: 1. Laboratory observation on 03/19/25 at 9:45 a.m. revealed the Sysmex XP 300 used for patient testing for CBC w/Diff. 2. A review of Form CMS-209 revealed one new testing person since the last survey date (testing person two). 3. A review of the laboratory's testing personnel policy revealed the following statements: "Technical personnel whose duties affect test data qualify will have the appropriate training for their position and job duties." "Each technical position will have specified job duties and a checklist to ensure each duty or performance level is attained before releasing the employee from the department training program. The written result/checklist of the training will be filed in the individual's personnel file." It also stated that the competency of testing personnel would be evaluated at least semiannually during the first year the individual tests patient specimens and then annually thereafter. 4. On the survey date (03/19/25), there was no documentation of training, semi-annual, or annual competency assessment for testing person two for use of the Sysmex XP300 CBC w/Diff instrument. 5. A review of the laboratory maintenance records for the Sysmex XP 300 revealed the initials of testing person two beginning on 03/21/24. 6. The technical consultant confirmed the</p>

survey findings during a phone interview on 03/24/25 at approximately 3:00 p.m. and confirmed that testing person two performed patient testing for CBC w/diff using the Sysmex XP 300 instrument.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on direct observation, a review of the Sysmex XP 300 operator's manual, the Sysmex XP 300 maintenance records, the laboratory procedure manual, and staff interview, the laboratory failed to identify and correct problems with documentation of weekly maintenance for five of 13 months reviewed for the Sysmex XP 300 CBC w /Diff instrument in 2024 and 2025. The findings include: 1. Laboratory observation on 03/19/25 at 9:45 a.m. revealed the Sysmex XP 300 used for patient testing for CBC w /Diff. 2. A review of the Sysmex XP 300 operator's manual revealed a weekly maintenance requirement to "Clean SRV tray." 3. A review of the laboratory's maintenance records revealed the following: The SRV tray cleaning was not documented on a weekly basis for July, August, October, and December 2024, or for February 2025. The technical consultant had reviewed all months, and no corrective action was documented for the missing documentation. 4. A review of the laboratory's quality assurance plan revealed the laboratory would "Effectively monitor, manage, and assess the total testing process including preanalytic, analytic, and post-analytic activities." "Identify problems in our laboratory and apply corrective action." 5. The technical consultant confirmed the survey findings during an interview on 03/19/25 at 1:30 p.m. Word Key: SRV=Sample Rotator Valve

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the Sysmex XP 300 CBC w/Diff instrument printouts, final patient test reports, and staff interviews, the laboratory failed to have an effective quality assessment review process in place to prevent errors in the final patient test report including units of measure in 2024 and 2025 and physical address in 2025. The findings include: 1. A review of the Sysmex XP 300 CBC w/Diff instrument printouts revealed the units of measure for the absolute granulocyte count, absolute lymphocyte count, and absolute monocyte/mixed count were $10^3/uL$. 2. A review of final patient test reports for CBC w/Diff revealed the units of measure were listed as "#" for the absolute granulocyte count, absolute lymphocyte count, and absolute monocyte count for patient MRN 5664305 (reported on 03/07/24), patient MRN 3463932 (reported on 05/06/24), and patient MRN 3277928 (reported on 02/10/25). 3. A review of the

patient test management document dated 07/01/24 revealed review of a CBC w/Diff report with no documented corrective action for the incorrect units of measure (patient MRN 3463932). The document used for review did not include monitoring for units of measure or verification of physical address. 4. Patient MRN 3277928 had the incorrect physical address (reported on 02/10/25). 5. During an interview with the technical consultant on 03/19/25 at 1:30 p.m., the technical consultant confirmed that the conducted review did not include review for correct units of measure for the absolute white blood cell differential parameters and stated that the laboratory's physical address was not updated after the move to the new location on 01/21/25. This confirmed the survey findings. Word key: 10³=thousand uL=microliter #=number