

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521160	(X3) Date Survey Completed 02/05/2025
Name of Provider or Supplier Syringa Hospital & Clinics	Street Address, City, State 607 W Main St, Grangeville, ID	
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 a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the laboratory manager on 2/4/2025, the laboratory failed to follow written procedures to assess testing personnel competency and to establish a procedure for competency assessments for the technical supervisor (TS) and general supervisor (GS) in 2023 and 2024. The findings include: 1. The CMS 209 identified six (6) testing personnel (TP) performing moderate and high complexity testing of which four (4) were new since the last inspection on 12/06/2022. 2. A review of laboratory procedures identified that the laboratory established a procedure to assess TP initial training, semiannual and annual competency but failed to establish a procedure for competency assessment performance for the TS and GS. 3. A review of training and competency assessment records identified that the laboratory failed to have an annual competency assessment for one (1) of two (2) TP in 2023. 4. A review of training and competency assessment records identified that the laboratory failed to have competency assessments for the TS and GS performed by the laboratory director in 2023 and 2024. 5. An interview with the laboratory manager on 2/4/2025 at 1:58 pm confirmed the above findings. 6. The laboratory reports performing 174,461 tests annually.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p>

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) documents from American Proficiency Institute (API) and an interview with the laboratory manager on 2/5/2025, the laboratory failed to review and evaluate PT scores that were less than 100% in 2024. The findings include: 1. A review of PT documents from API for the specialty of hematology for 2024 event two identified that the laboratory failed to evaluate results for sample XE-10 for basophils, eosinophils, IG absolute, IG percent, neutrophils, RDW-CV and RDW-SD with unacceptable results. 2. A review of PT documents from API for the specialty of chemistry for 2024 event two identified that the laboratory failed to evaluate results for sample BG-08 for glucose blood gas, sample CM-10 for creatine kinase-MB and sample CH-08 for total iron binding capacity with unacceptable results. 3. An interview with the laboratory manager on 2/5/2025 at 11:32 am confirmed that the laboratory failed to evaluate PT scores that were less than 100% in 2024. 4. The facility reports performing 6,446 complete blood count tests and 120,804 chemistry tests annually.

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 a review of proficiency testing (PT) documents from the American Proficiency Institute (API) and an interview with the laboratory manager on 2/5/2025, the laboratory failed to review and evaluate PT scores that were given an artificial score of 100% in 2024. The findings include: 1. A review of PT documents from API for the specialty of chemistry for 2024 event two identified that the laboratory failed to evaluate results for total iron sample CH-08 that was given an artificial score of 100% due to result variance. 2. A review of PT documents from API for the specialty of hematology for 2024 event two identified that the laboratory failed to evaluate results for vaginal wet preparation sample UA-04 that was given an artificial score of 100% due to no consensus. 3. An interview with the laboratory manager on 2/5/2025 at 11:36 am confirmed that the laboratory failed to evaluate PT scores that were given an artificial score. 4. The laboratory reports performing 117 total iron and 56 vaginal wet preparations tests annually.

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.

1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on a review of patient test records, laboratory policies, manufacturer's instructions, and interview with the laboratory manager on 2/5/2025, the laboratory failed to meet the requirements for the preanalytic system for forty-one of one hundred and eighty lactic acid specimens reviewed and one of twenty-three ammonia specimens reviewed. The findings include: 1. The laboratory failed to follow laboratory policies and manufacturer's instructions for specimen collection and handling: removing plasma from cells within 15 minutes after collection prior to analysis for forty-one of one hundred and eighty lactic acid specimens and within 30 minutes for one of twenty-three ammonia specimens in November 2024, December 2024, January 2025 and the first four days of February. See D5311

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of patient test records, laboratory policies, manufacturer's instructions, and interview with the laboratory manager on 2/5/2025, the laboratory failed to follow laboratory policy and manufacturer's instructions for specimen collection and handling: removing plasma from cells within the required time after collection prior to analysis for forty-one of one hundred and eighty lactic acid specimens and one of twenty-three ammonia specimens in November 2024, December 2024, January 2025 and the first four days in February. The findings include: Ammonia: 1. The manufacturer's instructions for use (Siemens EXL200) for ammonia states "the tube should be completely filled, stored tightly capped on ice and centrifuged without delay. Samples should be analyzed within 30 minutes of centrifugation." 2. A review of the laboratory's policy confirmed that the laboratory uses the manufacturer's instructions as part of their policy. 3. Patient test records were reviewed for November 2024, December 2024, January 2025 and the first four days of February. The following one of twenty-three reviewed patient reports were outside the 30 minute time frame: a. patient #03-25-023-0024 collected 1/23/2025 at 0900 received into the laboratory at 0933, 33 minutes. 4. An interview with the laboratory manager on 2/5/2025 at 3:50 pm confirmed the above findings. 5. The laboratory reports performing 80 ammonia test annually. Lactic Acid: 1. The manufacturer's instructions for use (Siemens EXL200) for lactic acid states "collect without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes." 2. A review of the laboratory's policy confirmed that the laboratory uses the manufacturer's instructions as part of their policy. 3. Patient test records were reviewed for November 2024, December 2024, January 2025 and the first four days of February. The following forty-one of one hundred and eighty reviewed patient reports were outside the 15 minute time frame: a. patient # 03-25-027-0002 collected on 1/27/2025 at 0620 received in

the laboratory at 0628, 28 minutes. b. patient # 03-25-024-0052 collected on 1/24/2025 at 1325 received in the laboratory at 1354, 29 minutes. c. patient # 03-24-316-0007 collected on 11/11/2024 at 0143 received in the laboratory at 0615, 4 hours and 32 minutes. d. patient # 03-25-007-0003 collected on 1/7/2025 at 0115 received in the laboratory at 0138, 23 minutes. e. patient # 03-25-010-0045 collected on 1/10/2025 at 1324 received in the laboratory at 1343, 19 minutes. f. patient # 03-25-014-0039 collected on 1/14/2025 at 1012 received in the laboratory at 1032, 20 minutes. g. patient # 03-24-340-0072 collected on 12/5/2024 at 1620 received in the laboratory at 1045, 25 minutes. h. patient # 03-24-313-0008 collected on 11/8/2024 at 0616 received in the laboratory at 0633, 17 minutes. i. patient # 03-24-314-0005 collected on 11/9/2024 at 0605 received in the laboratory at 0624, 19 minutes. j. patient # 03-25-029-0072 collected on 1/29/2025 at 1228 received in the laboratory at 1314, 46 minutes. k. patient # 03-24-340-0007 collected on 12/5/2024 at 0801 received in the laboratory at 0831, 30 minutes. l. patient # 03-24-331-0120 collected on 11/26/2024 at 1753 received in the laboratory at 1810, 17 minutes. m. patient # 03-24-358-0009 collected on 12/23/2024 at 0600 received in the laboratory at 0618, 18 minutes. n. patient # 03-24-341-0003 collected on 12/6/2024 at 0040 received in the laboratory at 0100, 30 minutes. o. patient # 03-24-317-0053 collected on 11/12/2024 at 1128 received in the laboratory at 1155, 27 minutes. p. patient #03-24-348-0002 collected on 12/13/2025 at 0629 received in the laboratory at 0655, 26 minutes. q. patient #03-25-032-0016 collected on 2/1/2025 at 0600 received in the laboratory at 0643, 43 minutes. r. patient #03-25-033-0004 collected on 2/2/2025 at 0600 received in the laboratory at 0809, 2 hours and 9 minutes. s. patient #03-25-035-0006 collected on 2/4/2025 at 0611 received in the laboratory at 0645, 34 minutes. t. patient #03-25-036-0014 collected on 2/5/2025 at 0623 received in the laboratory at 0645, 22 minutes. u. patient #03-25-029-0094 collected on 1/29/2025 at 1353 received in the laboratory at 1417, 24 minutes. v. patient #03-25-030-0006 collected on 1/29/2025 at 0600 received in the laboratory at 0749, 1 hour and 49 minutes. w. patient #03-24-330-0091 collected on 11/25/24 at 1715 received in the laboratory at 1759, 44 minutes. x. patient #03-24-357-0007 collected on 12/22/2024 at 2119 received in the laboratory at 2142, 23 minutes. y. patient #03-24-349-0003 collected on 12/14/2024 at 0625 received in the laboratory at 0643, 18 minutes. z. patient #03-25-350-0002 collected on 12/15/2024 at 0620 received in the laboratory at 0657, 37 minutes. aa. patient # 03-24-352-0010 collected on 12/17/2024 at 0617 received in the laboratory at 0638, 21 minutes. bb. patient # 03-24-366-0016 collected on 12/31/2024 at 0630 received in the laboratory at 0718, 48 minutes. cc. patient # 03-24-354-0016 collected on 12/19/2024 at 0808 received in the laboratory at 0825, 17 minutes. dd. patient # 03-25-004-0027 collected on 1/4/2025 at 2218 received in the laboratory at 2248, 30 minutes. ee. patient # 03-24-353-0003 collected on 12/17/2024 at 0622 received in the laboratory at 0642, 20 minutes. ff. patient # 03-24-347-0037 collected on 12/12/2024 at 1249 received in the laboratory at 1325, 36 minutes. gg. patient # 03-24-306-0073 collected on 11/1/2024 at 1619 received in the laboratory at 1716, 57 minutes. hh. patient # 03-25-030-0080 collected on 1/30/2025 at 1633 received in the laboratory at 1653, 20 minutes. ii. patient # 03-24-356-0006 collected on 12/21/2024 at 0058 received in the laboratory at 0132, 34 minutes. jj. patient # 03-24-356-0009 collected on 12/21/2024 at 0304 received in the laboratory at 0322, 18 minutes. kk. patient # 03-24-361-0059 collected on 12/26/2024 at 1655 received in the laboratory at 1722, 27 minutes. ll. patient # 03-25-011-0008 collected on 1/11/2025 at 0630 received in the laboratory at 0648, 18 minutes. mm. patient # 03-24-312-0035 collected on 11/7/2024 at 1026 received in the laboratory at 1048, 22 minutes. nn. patient # 03-25-029-0007 collected on 1/29/2025 at 0609 received in the laboratory at 0632, 23 minutes. oo. patient # 03-24-340-0050 collected on 12/5/2024 at 1328 received in the laboratory at 1350, 30 minutes. 4. An interview with the laboratory manager on 2/5/2025 at 3:50 pm

confirmed the above findings.. 5. The laboratory reports performing 693 lactic acid test annually.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's procedure, urinalysis reference manual, direct observation and an interview with the laboratory manager on 2/5/2025, the laboratory failed to include specimen processing for urine microscopic analysis in their policy and to centrifuge urine based on their reference manual. The findings include: 1. A review of the laboratory's policy, "Urinalysis (UA)" identified that the laboratory failed to include the centrifuge speed and time for urine microscopic analysis. 2. The reference manual in the laboratory, "A Handbook of Routine Urinalysis" by Sister Laurine Graff states "centrifuge 10-15 ml of urine at 2000 RPM (revolutions per minute) for five (5) minutes." 3. A direct observation of the VanGuard V6500 centrifuge used for urine microscopic analysis identified a PM performed in May 2024. The documents for the PM listed an RPM of 3,016 which identified that the laboratory failed to follow the centrifuge speed listed in the laboratory's reference manual. 4. An interview with the laboratory manager on 2/5/2025 at 5:01 pm confirmed that they did not have the centrifuge speed and time listed in their policy and they had not known the centrifuge speed. 5. The laboratory reports performing 1,642 urine microscopic analysis annually.