

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2144421	(X3) Date Survey Completed 05/09/2025
Name of Provider or Supplier Saint Francis Lab-Sand Springs Urgent Care	Street Address, City, State 102 S Main St, Sand Springs, OK	
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	The recertification survey was performed on 05/08,09/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and technical consultant at the conclusion of the survey.
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 records, written policies and procedures, and interview with the technical consultant, the laboratory failed to have a written policy to assess the competency of the technical consultant, based on the position responsibilities listed in Subpart M, for one of one person. Findings include: (1) On 05/08/2025, a review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the technical consultant based on the position responsibilities, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of September 2023 through the current date identified, although competencies, based on position responsibilities, had been performed for one of one person listed as the technical consultant on 04/04/2024 and 04/04/2025, the assessment policy was not available for review; (3) The findings were reviewed with the technical consultant who stated on 05/08/2025 at 09:16 am, a written policy was not available, although competencies had been performed for the position as stated above.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Cepheid GeneXpert Xpress analyzer during the review period of February 2024 through the current date. Findings include: (1) On 05/08/2025 at 12:00 pm, the technical consultant stated the laboratory performed SARS-CoV-2, Influenza A and B, and RSV (Respiratory syncytial virus) testing using the Cepheid GeneXpert Xpress analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Weekly: (i) Power down the GeneXpert Instrument and Computer (ii) Clean fan prefilter (b) Monthly: (i) Archive tests (ii) Purge tests (c) Quarterly: (i) Clean plunger rod and cartridge bays (ii) Clean instrument surfaces (iii) Replace fan filters (iv) Replace fan prefilters (3) A review of maintenance records from February 2024 through the current date identified weekly, monthly, and quarterly maintenance had not been documented as performed as follows: (a) Weekly: (i) Between 03/22/2024 and 04/04/2024 (ii) Between 04/19/2024 and 05/03/2024 (iii) Between 05/03/2024 and 05/17/2024 (iv) Between 05/17/2024 and 05/26/2024 (v) Between 06/25/2025 and 07/07/2025 (vi) Between 07/15/2024 and 08/01/2024 - Fan prefilter cleaning not performed (vii) Between 08/08/2025 and 08/18/2025 (viii) Between 10/05/2024 and 10/14/2024 (ix) Between 11/01/2024 and 11/11/2024 (b) Monthly: (i) Between 03/09/2024 and 05/12/2024 - Archive Tests not performed (ii) Between 05/31/2024 and 09/09/2024 - Archive Tests not performed (iii) Prior to 09/09/2024 - Purge Tests not performed (iv) Between 09/09/2024 and 11/01/2024 - Archive Tests not performed (v) Between 09/09/2024 and 02/01/2025 - Purge Tests not performed (vi) Between 12/31/2024 and 02/01/2025 - Archive Tests not performed (c) Quarterly: (i) Prior to 08/16/2024 - Clean Plunger rod and cartridge bays not performed (ii) Prior to 08/16/2024 - Clean Instrument Surfaces not performed (iii) Prior to 09/09/2024 - Replace fan filters not performed (iv) Prior to 09/09/2024 - Replace fan prefilters not performed (4) Interview with the technical consultant on 05/08/2025 at 02:40 pm confirmed the maintenance procedures had not been documented as performed as stated above.