

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2307419	<b>(X3) Date Survey Completed</b>  05/12/2026
<b>Name of Provider or Supplier</b>  Stockholm Medical Services	<b>Street Address, City, State</b>  401 N York St - Ste 4, Elmhurst, IL	
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>
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A) Based on review of laboratory policies and procedures, patient test reports, and interview with testing personnel (TP) #1; the laboratory failed to follow written policies and procedures that ensure optimum integrity of a patient's specimen from the time of collection of the specimen through completion of testing for three of three patients tested utilizing the laboratory-developed test (LDT) Urinary Tract Infection-Antibiotic Resistance Polymerase Chain Reaction (UTI-ABR PCR) in the specialty of microbiology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "SOP-029: UTI-ABR PCR Testing Procedure Using the BPX[™] DNA Direct Detect Kit", which stated, under "4. Sample Receipt and Initial Handling", "2. If not processed immediately, store the samples at 2-8[degrees Celsius] for up to 72 hours." 2. Review of patient test reports revealed the laboratory failed to perform UTI- ABR PCR patient testing within three days from collection of the specimen through completion of testing for three of three patients reviewed. i) Patient: 2046 Accession: 2928 Documented Date Collected: 02/20/2026 Documented Date Tested: 02/24/2026 ii) Patient: 2195 Accession: 4023 Documented Date Collected: 02/25/2026 Documented Date Tested: 03/10/2026 iii) Patient: 2228 Accession: 4056 Documented Date Collected: 02/26/2026 Documented Date Tested: 03/10/2026 3. Interview with TP #1 on 05/12/2026, at 11:48 am, confirmed the laboratory failed to follow written policies and procedures that ensure optimum integrity of a patient's specimen from the time of collection of the specimen through completion of testing for three of three patients tested utilizing the LDT UTI-ABR</p>

PCR in the specialty of microbiology. B) Based on review of laboratory policies and procedures, laboratory records, patient test reports, and interview with testing personnel (TP) #1; the laboratory failed to follow written policies and procedures that ensure optimum integrity of a patient's specimen from the time of collection of the specimen through completion of testing for two of three patients tested utilizing the laboratory-developed test (LDT) Respiratory Pathogen Panel-Polymerase Chain Reaction (RPP-PCR) in the specialty of microbiology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "SOP-030: Respiratory Pathogen PCR Testing Procedure Using the BPX[™] DUO Direct-Detect Kit", which stated, under "4. Sample Receipt and Initial Handling", "2. If not processed immediately, store the samples at 2-8[degrees Celsius]." 2. Review of laboratory records revealed the report titled "Summary Performance Report for Custom [LDT] Respiratory Pathogen Panel (RPP) Using the Atila Biosystems 96-Well Format", which summarized, under "Stability study" there was 100 percent concordance of results of tests run on day one and day five after collection of the respiratory swab in Amies collection media. 3. Review of patient test reports revealed the laboratory failed to perform RPP-PCR patient testing within five days from collection of the specimen through completion of testing for two of three patients reviewed. i) Patient: 1991 Accession: 2874 Documented Date Collected: 02/17/2026 Documented Date Tested: 02/25/2026 ii) Patient: 2206 Accession: 4034 Documented Date Collected: 02/25/2026 Documented Date Tested: 03/10/2026 4. Interview with TP #1 on 05/12/2026, at 11:48 am, confirmed the laboratory failed to follow written policies and procedures that ensure optimum integrity of a patient's specimen from the time of collection of the specimen through completion of testing for two of three patients tested utilizing the LDT RPP-PCR in the specialty of microbiology.