Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2330683	04/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Senior First Diagnostics Llc	1 Alberigi Dr, Jessup, PA	

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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification of performance specifications records, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to verify the required performance specifications for 3 of 3 microbiology assays (RT-PCR) performed on the Quant Studio 12K flex analyzer prior to reporting patient test results from 3/17/2026 to 4/9/2026. Findings Include: 1. The laboratory's Verification of Method Performance Specifications policy stated, "Laboratory Developed Tests (LDT) are validated as applicable for accuracy, precision, reportable range, sensitivity, specificity and patient reference range before any testing is performed." 2. On the day of the initial survey, 4/9/2026 at 11:35 am, review of the laboratory's verification of method performance specification records for the Quant Studio 12K flex analyzer (s/n 285882356) approved on 3/16/2026, revealed the laboratory failed to perform a reference range/normal value study appropriate for the laboratory's patient population for the following 3 of 3 microbiology RT-PCR assays prior to reporting patient test results from 3/17/2026 to 4/9/2026: - Respiratory Open Array (RPP-OA) - Urinary Assay (UTI panel) - Antimicrobial Resistance Assay

	(ABR) 3. Review of the laboratory's test logs revealed the laboratory performed 20 RPP-OA, 15 UTI panels, and 14 ABR assays from 3/17/2026 to 4/9/2026. 4. The LD confirmed the findings above on 4/9/2026 at 1:00 pm.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the Laboratory Director (LD), the laboratory failed to include pertinent reference intervals/normal values on 4 of 4 patient test reports when microbiology test results were reported from 3/17/2026 to the day of the initial survey. Findings include: 1. On the day of the initial survey, 4 /9/2026 at 12:39 pm, review of 4 of 4 patient test reports revealed the laboratory failed to include pertinent reference intervals/normal values for the following microbiology test results reported from 3/17/2026 to 4/9/2026: - Respiratory Open Array (RPP-OA) - Urinary Assay (UTI panel) - Antimicrobial Resistance Assay (ABR) 2. Review of the laboratory's test logs revealed the laboratory performed 20 RPP-OA, 15 UTI panels, and 14 ABR assays from 3/17/2026 to 4/9/2026. 3. The LD confirmed the findings above on 4/9/2026 at 1:00 pm.