Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2247336	10/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Srs 2 Llc	235 W Lorenz Blvd Ste C, Jackson, MS	

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) 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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for LumiraDx SARS-CoV-2 RNA STAR Complete assay, quality control records for LuminUltra GeneCount Q-96 Quantitative Polymerase Chain Reaction (qPCR) instruments Serial #MDW6.6.19E-651288 and Serial #MDW6.619E-651275, located on the laboratory's Mobile Unit Vehicle Identification Number (VIN) 4FGB44531KC151920, and LuminUltra GeneCount Q-96 qPCR instruments Serial #BYQ6.619E-651203 and Serial #BYQ6. 619E-651206, located on the laboratory's Mobile Unit VIN 1FVHGEBG8JLJK3197, and patient specimen test counts for these instruments, the laboratory failed to establish performance specifications for these four instruments, to include accuracy, precision, analytical sensitivity, and analytical specificity (including interfering substances) before performing Severe Acute Respiratory Syndrome-Coronavirus-2 (SARS-CoV-2) testing on a total of 6,483 patient specimens from 2/14/22 through 9 /22/22. Findings include: Review of the manufacturer's instructions for LumiraDx SARS-CoV-2 RNA STAR Complete assay revealed performance specifications were not provided by the manufacturer for the LuminUltra GeneCount Q-96 qPCR

	instrument, requiring establishment of performance specifications for SARS-CoV-2 testing on the LuminUltra GeneCount Q-96 qPCR instruments listed below, in use on Mobile Unit VIN 4FGB44531KC151920 and Mobile Unit VIN 1FVHGEBG8JLJK3197. (1) Mobile Unit VIN 4FGB44531KC151920 Review of quality control records for LuminUltra GeneCount Q-96 qPCR instruments Serial Numbers MDW6.6.19E-651288 and MDW6.619E-651275 revealed these instruments were in use for SARS-CoV-2 testing on a total of 3,219 patient specimens, with the LumiraDx SARS-CoV-2 RNA STAR Complete assay, for a total of 137 days from 2 /14/22 through 9/22/22. (2) Mobile Unit VIN 1FVHGEBG8JLJK3197 Review of quality control records for LuminUltra GeneCount Q-96 qPCR instruments Serial Numbers BYQ6.619E-651203 and BYQ6.619E-651206 revealed these instruments were in use for SARS-CoV-2 testing on a total of 3,264 patient specimens, with the LumiraDx SARS-CoV-2 RNA STAR Complete assay, for a total of 37 days from 3/4 /22 through 7/14/22. The only documentation available for these LuminUltra GeneCount Q-96 qPCR instruments was a comparison with Applied Biosystems QuantStudio 5 qPCR instrument, Serial #272533138, in use at the Jackson, Mississippi location. However, there was no documentation of the establishment of performance specifications for these four LuminUltra GeneCount Q-96 qPCR instruments, to include accuracy, precision, analytical sensitivity, and analytical specificity (including interfering substances) for the LumiraDx SARS-CoV-2 RNA STAR Complete assay.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: 1. Based on review of quality control records for Applied Biosystems QuantStudio 5 qPCR instruments, Serial #272533138 and Serial #272533256, on the day of the survey, 10/6/22, and interview with General Supervisor #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 10/6/22 at 4:45 p.m., the technical supervisor failed to document review of quality control records, for evaluation of the competency of the staff, for these instruments since testing began on Serial #272533138 on 1/26/22 and on Serial #272533256 on 4/26/22 at the Jackson, Mississippi location. Findings include: Review of quality control records for Applied Biosystems QuantStudio 5 qPCR instruments, Serial #272533138 and Serial #272533256, on the day of the survey, 10/6/22, revealed no documentation of review by the technical supervisor, for evaluation of the competency of the staff for performing testing with these instruments, since testing began on Serial #272533138 on 1/26/22 and on Serial #272533256 on 4/26/22 at the Jackson, Mississippi location. In an interview on 10/6/22 at 4:45 p.m., General Supervisor #2 confirmed there was no documentation of review by the technical supervisor of these quality control records. 2. On the day of the survey, 10/6/22, there were no quality control records available for review for the LuminUltra GeneCount Q-96 Quantitative Polymerase Chain Reaction (qPCR) instruments in use on Mobile Unit VIN 4FGB44531KC151920 and Mobile Unit VIN 1FVHGEBG8JLJK3197. Based on review of the quality control records later provided by the laboratory for LuminUltra GeneCount Q-96 qPCR instruments Serial Numbers MDW6.6.19E-651288 and MDW6.619E-651275, in use on Mobile Unit VIN 4FGB44531KC151920 from 2/14

	/22 through 9/22/22, and for LuminUltra GeneCount Q-96 qPCR instruments Serial Numbers BYQ6.619E-651203 and BYQ6.619E-651206, in use on Mobile Unit VIN 1FVHGEBG8JLJK3197 from 3/4/22 through 7/14/22, the technical supervisor failed to document review of these quality control records, for the evaluation of the competency of the staff, until after the survey on 10/6/22. Findings include: (1) Review of the quality control records provided by the laboratory on 10/26/22 for testing performed on the LuminUltra GeneCount Q-96 qPCR instruments Serial Numbers MDW6.6.19E-651288 and MDW6.619E-651275, in use on Mobile Unit VIN 4FGB44531KC151920, revealed these instruments were used for testing for a total of 137 days from 2/14/22 through 9/22/22, when a total of 3,219 patient specimens were tested for SARS-CoV-2. There was no documentation of review by the technical supervisor, for evaluation of the competency of the staff for performing testing with these instruments, until 10/26/22. (2) Review of the quality control records provided by the laboratory on 11/8/22 for testing performed on the LuminUltra GeneCount Q-96 qPCR instruments Serial Numbers BYQ6.619E-651203 and BYQ6.619E-651206, in use on Mobile Unit VIN 1FVHGEBG8JLJK3197, revealed these instruments were used for testing for a total of 37 days from 3/4/22 through 7/14/22, when a total of 3,264 patient specimens were tested for SARS-CoV-2. There was no documentation of review by the technical supervisor, for evaluation of the competency of the staff for performing testing with these instruments, until 11/7 /22.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS 209 Laboratory personnel form and personnel records since testing began on 01/26/2022, the technical supervisor failed to evaluate and document the performance of Laboratory Testing Personnel semiannually during the first year these individuals performed high complexity testing. Findings include: Review of the CMS 209 Laboratory personnel form and personnel records since 01/26 /2022 when high complexity testing began revealed no semiannual evaluations by the technical supervisor documenting the performance of Laboratory Testing Personnel #1, #2, #3, #4, #5, #6, #8, and #9 since the laboratory began performing high complexity testing on 01/26/2022. 487 patient samples were tested in September 2022 after the semiannual evaluations were due.