Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2209968	10/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
R & R Clinical Lab Inc	1308 Macom Dr, Naperville, IL	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP 1), the laboratory failed to perform biannual method accuracy for high complexity antibody staining on the StatLab Quantum HDx at least twice a year in 2022. Findings Include: 1. Review of the laboratory's proficiency testing (PT) manual revealed the following: a. "R&R Clinical Laboratory participates biannually in a Blind Study where 5 antibodies are run on known positive control slide and they are compared to a different lab, who also runs the same 5 antibodies on known positive control slides and the two groups are assessed on 4 different criteria as acceptable or unacceptable." 2. The laboratory failed to produce written documentation of biannual method accuracy in 2022 for 101 of 101 of the immunohistochemical (IHC) antibody stains performed on the StatLab Quantum HDx analyzer as listed on the R & R Clinical Lab Histology Request Form. 3. On 10/13/2022 at 2:25 p.m., TP 1 stated the laboratory failed to complete biannual method accuracy as indicated in laboratory's PT manual.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3)

	The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of specimen documentation logs and interview with testing personnel (TP 1), the laboratory failed to ensure complete and accurate test requisition information for specimen submission for five of five dates reviewed in 2022. Findings include: 1. Review of the patient specimen documentation logs revealed the laboratory failed to provide a time stamp on the specimen tracking logs for five of five dates reviewed for specimen submission. (03/15/2022, 04/25/2022, 06/14/2022, 09/13/2022 and 09/29/2022) 2. Review of the specimen documentation log dated 03/15/2022 revealed the laboratory failed to confirm submitting provider identification for five of five patients. (Accession #: 101-NG-22-00038, 101-NG-22-00039, 101-SP-22-00860, 101-SP-22-00864, and 101-SP-22-00867) 3. Review of the specimen documentation log dated 04/25/2022 revealed the laboratory failed to confirm the names of the tests requested from the provider for five of five patients. (Accession #: 101-SP-22-01364, 101-SP-22-01366, 101-SP-22-01367, 101-SP-22-01369, and 101-SP-22-01370) 4. Review of the specimen documentation log dated 06/14/2022 revealed the laboratory failed to confirm a contact person to report alert values from the provider for five of five patients. (Accession #: 101-SP-22-01963, 101-SP-22-01965, 101-SP-22-01968, 101-SP-22-01972, and 101-SP-22-01976) 5. Review of the specimen documentation log dated 09/13/2022 revealed the laboratory failed to confirm the name of the requesting physician from the provider for five of five patients. (Accession #: 22 /SU1381, 22/SU1383, 22/SU1385, 22/SU1386, and 22/SU1388) 6. Review of the specimen documentation log dated 09/29/2022 revealed the laboratory failed to confirm the confirm two patient identifiers from the provider for six of six patients. (Accession #: 100-SW-22-1139, 100-SW-22-1137, 100-SW-22-1132, 100-SW-22-1140, 100-SW-22-1143, and 100-SW-22-1142) 7. On 10/13/2022 at 2:00 p.m., the above findings were confirmed by TP 1.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, Laboratory Personnel Report (CMS-209), and interview with testing personnel (TP 1), three of four individuals failed to meet the testing personnel qualification requirements for high complexity histopathology testing. Findings Include: 1. Review of education records for testing personnel listed on CMS-209 (10/03/2022) revealed three of four TP (TP 1, TP 3, and TP 4) failed to meet the qualification requirements for high complexity histopathology testing. (Refer to D6171)

D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet

	the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory records, Laboratory Personnel Report (CMS-209), and interview with testing personnel (TP 1), the laboratory failed to qualify three of four testing personnel for high complexity histopathology testing. Findings Include: 1. Review of education records for testing personnel listed on CMS-209 (10/03/2022) revealed three of four TP failed to meet the qualification requirements for high complexity histopathology testing. a. TP 1 - Transcripts failed to document credits required in biology and chemistry to qualify TP. b. TP 3 - Transcripts failed to document credits required in biology and chemistry to qualify TP. c. TP 4 - Transcripts failed to document credits required in biology and chemistry to qualify TP. 2. On 10/13/2022 at 3:00 p.m., TP 1 confirmed Finding 1.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on the review of laboratory records, patient specimen documentation logs, and interview with testing personnel (TP 1), the laboratory testing personnel failed to follow the laboratory's procedures for specimen handling and processing for five of five dates reviewed in 2022. Findings include: 1. Review of the laboratory's specimen handling procedures manual revealed: a. "Specimen Receiving: Time stamp each specimen on its requisition." b. "Specimen Receiving: Ensure requisition patient data and specimen labels match. If not, an Error Report form is filled out and it is returned to the originating lab." c. "Receiving Tissue: Record patient data under each column heading (Received Date, Collection Date, Patient Name, Accession number, Requesting test, CPT Code, Charges)" d. "Specimen Labeling: All specimen labels received at R & R Clinical Lab will include at least the following patient information (excluding research specimens): Name (or unique patient identifier), DOB, Specimen source (aka Tissue type)" 2. Review of patient specimen documentation logs and the laboratory's specimen handling procedure revealed the laboratory failed to follow the items described in Finding 1 for five of five dates reviewed for specimen submission. 03/15/2022, 04/25/2022, 06/14/2022, 09/13/2022, and 09/29/2022. (Refer to D5305) 3. On 10/13/2022 at 2:00 p.m., the above findings were confirmed by TP 1.