Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2237355	05/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Resolve Molecular Diagnostics Llc	2920 Kingman Street, Suite 120, Metairie, LA	

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	An Initial survey was performed at Resolve Molecular Diagnostics, LLC, CLIA ID 19D2237355, on May 20, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 the laboratory's policies and twice a year verification records as well as interview with personnel, the laboratory failed to verify the accuracy of all tests performed in microbiology at least twice a year for two (2) of two (2) events reviewed from 2023. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "The appropriate specimen type for PT includes CAP/commercial survey specimens, previously tested patient samples, or other previously analyzed DNA obtained for alternative proficiency testing. The appropriate specimen type for proficiency testing includes commercial survey specimens and/or in-house prepared blinded alternative proficiency testing (prepared by RMDx TN or in-house in Metairie). Alternative PT testing is instituted when commercial products do not cover the targets on the custom panel." 2. Review of the 2023 proficiency testing (PT) records revealed the laboratory performed split sample testing with another laboratory twice during 2023, but did not verify the following targets for accuracy: Coronavirus HKU1 Coronavirus NL63 Coronavirus 229E Coronavirus OC43 Human parainfluenza virus 2 Human parainfluenza virus 3 Influenza A RSV SARS-CoV-2 Staphylococcus aureus Streptococcus pneumoniae Mycoplasma pneumoniae 3. In interview on May 20, 2024 at 1:04 p.m., the Testing Personnel confirmed not all tests performed by the laboratory were verified for accuracy twice annually.

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 the laboratory's test menu and test requisition as well as interview with personnel, the laboratory failed to ensure test requisitions included all tests performed at the laboratory. Findings: 1. Review of the laboratory's test menu revealed the laboratory included the following tests in the Respiratory Pathogen Panel (RPP): Adenovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, Enterovirus, Human Metapneumovirus, Human parainfluenza virus 1, Human parainfluenza virus 2, Human parainfluenza virus 3, Human parainfluenza virus 4, Influenza A, Influenza A/H3, Influenza A/H1-2009, Influenza B, Rhinovirus, RSV, SARS-CoV-2, Staphylococcus aureus, Streptococcus pneumoniae, and Mycoplasma pneumoniae. 2. Review of the laboratory's test requisition revealed the following tests were not included in the RPP: Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, Human parainfluenza virus 2, Human parainfluenza virus 3, Influenza A/H3, Influenza A/H1-2009, Rhinovirus, SARS-CoV-2, Staphylococcus aureus, and Streptococcus pneumoniae. 3. Further review of the laboratory's test requisition revealed the following tests were included as part of the RPP, but were not performed: Human Bocavirus, Chlamydia pneumoniae, Bordatella parapertussis, and Bordatella pertussis. 4. In interview on May 20, 2024 at 12:22 p.m., the Testing Personnel confirmed the lab requisition did not include all tests performed by the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's performance specification studies, policies, and interview with personnel, the laboratory failed to establish a policy related to actions to take for inoperable test systems that did not exceed the laboratory's sample stability requirements. Findings: 1. Review of the laboratory's performance specification studies revealed the laboratory established the following stability requirements: a) Urine: 48 hours at Room temperature (15-25 degrees Celsius); 72 hours at 2-4 degrees Celsius b) Respiratory samples: 72 hours -20 to 35 degrees Celsius; except May through September samples must be delivered and/or transported within 48 hours on ice packs 2. Review of the laboratory's "Computer Malfunction" policy revealed "Note: Perform the following if systems are to be down more than 7 days. 1. Forward all specimens to a reference laboratory. Fill in IFRM-4000001: Computer Malfunction Notification." The actions described exceeds the laboratory's sample stability requirement. 3. In interview on May 20, 2024 at 1:53 pm, the Testing Personnel stated if the laboratory's instrument was down/inoperable, clients would be notified and samples sent to a reference laboratory before seven (7) days as listed in the policy.
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 observation of surveyors, review of policies, performance specification records, and interview with personnel, the laboratory failed to have complete performance specification studies for Microbiology and Antibiotic Resistance Panel (ABR) testing on the QuantStudio 12k Flex instrument. Findings: 1. Observation by surveyors during the laboratory tour on May 20, 2024 at 9:23 am revealed the laboratory utilizes the QuantStudio 12k Flex for Microbiology, to include respiratory pathogen panel (RPP), urinary tract infection (UTI) panel, and ABR testing of the following pathogens and antibiotics: Adenovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronaviurs OC43, Enterovirus, Human Metapneumovirus, Human parainfluenza virus1, Human parainfluenza virus 2, Human parainfluenze virus 3, Human parainfluenza virus 4, Influenza A, Influenza A/H3, Influenza A/H1-2009, Influenza B, Rhinovirus, RSV, SARS COV-2, Staphylococcus aureus,

	Streptococcus pneumoniae, Mycoplasma pneumoniae, Acinetobacter baumannii, Citrobacter freundii, Enterobacter aerogenes, Enterobacter cloacae, Escherchia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens, Aerococcus urinae, Coagulase Negative Staphylococcus, Staphylococcus saprophyticus, Staphylococcus aureus, Streptococcus agalactiae, Enterococcus faecalis, Enterococcus faecium, Mycoplasma hominis, Candida albicans, Candida glabrata, Candida parapsilosis, Beta lactamase, Carbapenems and Beta-lactamase, Glycopeptides, Macrolides, Quinolone and Fluoroquinolone, Sulfonamide, and Trimethoprim. 2. Review of the laboratory's "Test Method Validation/Verification" policy revealed "test method validation parameters are as follows: Accuracy-the closeness of agreement of a single genotype measurement to the 'true genotype'; Precision/Reproducibility-the percentage of specimens that yields the identical genotype calls in multiple analytical runs, performed by the same technician (inter), performed by different technicians (intra); Reportable Range-DNA concentration or DNA input to accurately and precisely yield the same genotype (often pre-determined by the manufacture); Reference Range-range of results expected in the normal population or minor allele frequency (MAF); Analytical Sensitivity/Limit of Detection-the range of input amounts of DNA for which a method can accurately assign genotype calls to specimens; Analytical Specificity-the ability of a method to determine specifically the genotype in the presence of potentially interfering genes; Clinical Performance Characteristics-i.e. Transitional monographs." 3. Review of the laboratory's UTI and ABR performance specification studies revealed the laboratory did not establish the following: a) Reference Range: applicable normal value b) Specificity studies, to include, interfering substances for urine c) Stability studies that included the complete list of organisms and antibiotic medication tested by the laboratory 4. In interview on May 20, 2024 at 11:27 am, the Testing Personnel stated she was unsure why the UTI reference range information referred to swabs and was not applicable to urine testing. 5. In further interview on May 20, 2024 at 11: 47 am, the Testing Personnel confirmed the laboratory's performance specifications for UTI testing did not include the identified items. 6. Review of the laboratory's RPP performance specification studies revealed the laboratory did not establish the following: a) Specificity studies, to include, interfering substances for respiratory samples b) Stability studies that included detection of the complete list of organisms tested by the laboratory 7. In interview on May 20, 2024 at 10:55 a.m., the Testing Personnel stated she did not perform specificity studies. She confirmed not all organisms on the laboratory's testing menu were detected in the stability studies.
D5807	TEST REPORT CFR(s): 493.1291(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 final test reports and interview with personnel, the laboratory failed to define the normal value for urinary tract infection (UTI) testing on three (3) of three (3) patient final test reports reviewed. Findings: 1. Review of the following random selection of patient final test reports revealed the laboratory included "Reference Range:Detected/Not Detected" on their patient final test reports, not the reference range/normal value for UTI testing: Patient L24000163 Patient

	L24000065 Patient L23000237 2. In interview on May 20, 2024 at 11:47 am, the Testing Personnel confirmed the laboratory included the reportable values, not the normal values for UTI testing on patient final test reports.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D5305.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, performance specification studies, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for testing. Refer to D5423.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5217.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent

	information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5807.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure one (1) of one (1) Testing Personnel had documentation of training prior to respiratory panel (RPP) patient testing. Findings: 1. In interview on May 20, 2024 at 9:15 am, the Testing Personnel stated the validation for the respiratory panel testing was performed in August 2022 and patient testing began January 8, 2024. 2. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the laboratory had one (1) Testing Personnel. 3. Review of the laboratory's "Competency Assessments" policy revealed "For non-waived testing: During the first year of a laboratory personnel's duties, competency must be assessed initially, and at least semi-annually. After laboratory personnel have performed his/her duties for one year, competency must be assessed at least annually." 4. Review of personnel records revealed the Testing Personnel did not have documentation of training for respiratory panel testing. 5. In interview on May 20, 2024 at 10:03 am, the Testing Personnel stated she did not have a trainer for the respiratory testing because she had experience performing the test. The Testing Personnel confirmed she did not have documentation of training for RPP testing.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a complete procedure manual was available to all personnel. Refer to D5403.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the

	laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure test requisitions included all tests performed at the laboratory. Refer to D5305. 2. The laboratory failed to establish a policy related to actions to take for inoperable test systems that did not exceed the laboratory's sample stability requirements. Refer to D5403. 3. The laboratory failed to define the normal value for urinary tract infection (UTI) testing on three (3) of three (3) patient final test reports reviewed. Refer to D5807.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance studies. Refer to D5423.