Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2188773	10/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Basis Diagnostics Inc	2688 Middlefield Rd, Ste A, Redwood City, CA	

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
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour and interview with the laboratory's director (LD) and technical supervisor (TS) on October 1, 2024; it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen processing of samples for the molecular detection of various bacterial and viral organisms. The findings include: 1. The laboratory uses molecular methods to identify the presence of bacterial and viral organisms in urine (UTI Panel) and other body fluids (Sars-CoV-2, RSV, Influenza A and B, etc.). 2. During the laboratory tour at approximately 12:25 p.m. the surveyor observed that the areas (Biosafety cabinet, processing area, and preparation of reagents and controls) assigned for conventional molecular testing using the polymerase chain reaction (PCR) method lacked decontamination logs documentation. 3. During an interview on October 1, 2024, at approximately 12:30 p. m. the LD and TS confirmed the laboratory failed to document decontamination procedures; therefore, failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples. 4. The laboratory testing declaration form signed by the LD stated that the laboratory performs approximately 6,000 laboratory tests using the PCR method to detect bacterial and viral organisms.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a

	uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's Polymerase Chain Reaction (PCR) testing area for the presumptive detection of UTI bacterial and viral panel, RSV, SARS CoV-2 (COVID19), etc., and interviews with the laboratory's director (LD) and technical supervisor (TS) on October 1, 2024 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the detection of various bacterial and viral agents of infection using manual methods for specimen processing, preparation of the master-mix, controls, reagents, and addition of template. 2. During the laboratory tour on October 1, 2024, at approximately 1:00 p. m. the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same room/area without unidirectional flow. 3. The LD and TS confirmed by interview that the laboratory's molecular PCR testing was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 6,000 Real Time PCR molecular diagnostic tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory's tour reagent materials used in the laboratory and interviews with the laboratory director (LD) and technical supervisor (TS); it was determined that the laboratory failed to label various reagents used in the laboratory to indicate the reagent's name, opening, preparation, and expiration dates when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory tour on October 1, 2024, at approximately 1:00 pm.; no opening, preparation, or expiration date labels were used or documented for various reagents (distilled water, 70% alcohol, bleach, etc.) used throughout the laboratory. 2. The laboratory's LD and TS affirmed in an interview conducted on 10/1/2024, at approximately 1:15 p.m. that the reagents mentioned in 1. above were not labeled with the received date, opening, preparation, and expiration dates or documented in a reagent preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 9,000 clinical tests for which various reagents were not labelled.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedure, four (4) randomly selected patient records, and interviews with laboratory director (LD) and technical supervisor (TS); it was determined that the laboratory failed to perform and document preventive maintenance (PM) and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for small equipment used in the laboratory for sample testing. The findings included: 1. At the time of survey on 10/1//2024, based on the surveyors' observation during the laboratory tour and review of records documentation at approximately 1:30 p.m., it was determined that the laboratory failed to perform PM and calibration on small equipment used in the laboratory for sample processing: thermometers, centrifuges, rotators, and vortexes. 2. The LD and TS affirmed on October 1, 2024, at approximately 1:00 p.m. that maintenance and calibration was missed for the equipment mentioned in #1. 3. According to the laboratory's testing declaration submitted by the LD, the laboratory performed approximately 6,000 microbiology and 3,000 diagnostic immunology samples annually for which no preventive maintenance of small equipment was performed.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, proficiency testing records, four (4) randomly selected patients test records, observation during the laboratory tour, and interviews with the laboratory director and technical supervisor on October 1, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical and postanalytic phases of the laboratory testing were monitored. See D3003, D3005, D5415, and D5429.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on the surveyors' direct observations of the laboratory's UTI bacterial and viral organisms panel, Influenza A and B, Respiratory Syncytial Virus (RSV) RNA, and SARS- CoV-2 (COVID19) detection testing processes and interviews with the

	laboratory's director and technical supervisor on October 1, 2024; the laboratory director failed to ensure that the physical plant to conduct polymerase chain reaction (PCR) testing of the laboratory is appropriate. Findings include See D3005.