

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2189600	(X3) Date Survey Completed 10/25/2022
Name of Provider or Supplier Sirona Lab Diagnostics Inc	Street Address, City, State 11755 Victory Blvd Ste 108, North Hollywood, 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	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: . Based on review of the laboratory written procedures, interview with the technical consultant (TC) and testing personnel (TP) on October 25, 2022, at approximately 12:30 p.m.; the laboratory failed to establish policies and procedures to ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's Polymerase Chain Reaction (PCR) testing processes of respiratory specimens using the BIOFIRE technique were minimized, The findings include: 1. In review of the laboratory's written procedures for its PCR test processes, the laboratory failed to have written protocols for decontamination to ensure that patient's specimens, equipment, instruments, reagents, materials, and supplies were not cross contaminated. 2. In an interview with the TC and TP on October 25,2022 @ approximately 13:00 p.m., when asked if the laboratory conducted any PCR contamination detection protocols, the TC could not provide decontamination policy or documentation as per manufacturer recommendations. The laboratory's testing declaration form, signed by the Laboratory Director on 10/25/2022, stated that the laboratory performs approximately 48,000 tests, annually.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p>

This STANDARD is not met as evidenced by:
. Based on review of six (6) patient reports, laboratory's policies and procedures, interview with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to document the time a specimen is collected and received by the laboratory. The findings include: 1. The laboratory failed to document the time of collection and the time specimens were received. 2. TC presented the laboratory's requisition slip which they provide to their ordering physicians. The requisition slip had no space requesting the time of specimen collection. 3. On 10/25/22 @approximately 13:00 the TC affirmed that the requisition slip had no space to document the time specimen was collected or received in the laboratory. The laboratory's testing declaration form, signed by the Laboratory Director on 10/25/2022, stated that the laboratory performs approximately 48,000 tests, annually.

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 lack of documentation to establish policies and procedures to minimize cross-contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for testing the presence of pathogens by the Polymerase Chain Reaction (PCR) using the BIOFIRE method and; the lack of specimen collection and receiving time; it was determined that the laboratory director failed to ensure that testing systems developed and used for PCR detection performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing in a safe environment. See: D5313 and D3003. See: D5313 and D3003