Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2159950	02/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Eurofins Donor & Product Testing, Inc	615 Elsinore Place, Suite 215, Cincinnati, OH	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and an interview with General Supervisor (GS) #2, the laboratory failed to have a qualified Technical Supervisor (TS) attest to the routine integration of the proficiency testing samples into the patient workload using the laboratory's routine methods in 2019 and 2020. All patient microbiology, diagnostic immunology and immunology testing performed in this laboratory from 05/14/2019 to 02/24/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the CMS-209 Personnel Report Form found the Laboratory Director (LD) listed as performing the duties of the TS. 2. Review of the "VQA-020 Laboratory Director's Acknowledgement of Delegation of Duties" found the following statement: "The following duties may be delegated to a senior department member (Director, Department Manager, Supervisor, or other trained and qualified individual): ...Submission of external proficiency test results to accrediting bodies" 3. Review of attestation pages from 2019 found the General Supervisor #1 attested for 13 out of 13 proficiency testing events in 2019, 15 out of 15 proficiency testing events in 2020 and the General Supervisor #2 attested for two out of two proficiency testing events in 2021. 4. An interview with GS #2 on 02/24/2021 at 1:15 PM confirmed GS #1 and GS #2 attested by signature to the routine integration of the samples into the patient workload using the laboratory's routine methods.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS) #2, the laboratory failed to establish and follow written policies and procedures to assess the competency for three out of five Testing Personnel (TP). All patient microbiology, diagnostic immunology and immunology testing performed by TP #2, TP #3 and TP #4 in this laboratory from 05/14/2019 to 02/24/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "VGN-016 Ensuring Competency for VRL Europhins Personnel" policies and procedures, provided 02/02/2021 prior to the date of the inspection found the following statements: "3.2.1. Following initial training and competency evaluation, the employee will be evaluated twice during the first year of employment and annually thereafter. The process is designed to be completed within a 30 day period from the date it is started/due. * (Example: For an employee who started on September 1, 2019, a competency would be performed following initial training, a 6 month competency to be completed by March 31, 2019 and an annual competency to be completed by September 30, 2020.)" 2. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 02/24/2021 and provided on the date of the inspection, revealed five TP. 3. Review of the laboratory's competency assessment for 2019-2020 found the following dates for TP #2, TP #3 and TP #4: TP Hired Six month competency assessment #2 08/09/2019 06/2020 #3 06/04/2019 No six month #4 01/13/2020 No six month 4. The GS #2 confirmed the laboratory did not follow the competency assessment policy and procedure for TP#2, TP#3 and TP#4 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/24/2021 at 10:35 AM. *March 31 2019 should state March 31 2020. Date typo within the policy and procedure.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on document review, and interviews with the General Supervisor (GS) #2 and the Quality Systems Manager (QSM), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. All patient microbiology, diagnostic immunology and immunology testing performed in this laboratory from 05/14/2019 to 02/24/2021 had the potential to be affected by this deficient practice. Findings include: 1. Review of the VQA-003 Internal audits policy and procedure found the following statement under section 3 Process: "3.1.1...Audit preparation includes but is not limited to review of: 3.1.1.5. Staff and record keeping of training." 2. Review of the "Certificate of Internal Quality Audit, VRL-CIN-2020" dated August 17, 2020 - August 31, 2020 revealed the following: "The following areas were included within the scope of the audit: ...Training records" 3. The inspector

	requested documentation of initial, six month and annual competency assessments of all testing personnel for 2019-2020. The GS #2 was unable to provide records of the initial and the six month competency assessments for testing personnel #2, testing personnel #3 and testing personnel #4 as requested. 4. Interviews with the GS #2 and the QSM on 02/24/2021 at 10:40 AM, confirmed quality assessment was not performed as stated within VQA-003 and the Certificate of Internal Quality Audit VRL-CIN-2020.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS) #2, the current Laboratory Director (LD) failed to ensure policies and procedures were approved, signed and dated before use. All patient microbiology, diagnostic immunology and immunology testing performed in this laboratory from 10/01/2020 to 02/24/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedures provided on 02/04/2021 and on the date of the inspection revealed the following approval dates from the current LD: "VGN-001 VRL Training Procedure" electronically approved 12/07/2020 "VGN-002 Internal and External Proficiency Testing" electronically approved 12/07 /2020 "VQA-003 Internal Audits" electronically approved 01/20/2021 "VGN-016 Ensuring Competency for VRL Europhins Personnel" electronically approved 12/07 /2020 "VID-116 Internal proficiency Testing for Infectious Disease" electronically approved 01/20/2021 2. The GS #2 confirmed all policies and procedures were not approved, signed and dated by the current LD before use. The interview occurred on 02/24/2021 at 11:50 AM.