Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2159950	01/30/2023
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
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 record reviews and an interview with General Supervisor (GS) #3, the Laboratory Director (LD) failed to ensure the employment of qualified testing personnel. This deficient practice had the potential to affect 7,062 patients tested between 02/24/2021 to 01/30/2023 in the subspecialties of virology, syphilis serology, general immunology, and ABO and Rh testing. Findings Include: 1. Review of the Form CMS-209 signed and dated by the LD on 01/31/2023 found nine GS and 39 Testing Personnel (TP) listed. 2. On the date of inspection the inspector requested education documents from GS #3 for all GS and TP listed on the form CMS-209. 3. GS #3 was unable to provide the requested education documents for GS#4, GS#5, GS#9, TP#9, TP#10, TP#11, TP#12, TP#13, TP#16, TP#18, TP#23, TP#28, TP#29, TP#30, TP#31, TP#32, TP#33, TP#34, TP#35, TP#36, TP#37, TP#38 and TP#39. The interview occurred on 01/30/2022 at 12:05 PM.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11)

	The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on record reviews and an interview with General Supervisor (GS) #3, the Laboratory Director (LD) failed to employ a sufficient number of lab personnel with the appropriate education and either experience or training to provide consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This deficient practice had the potential to affect 5,121 patients tested between 04/01/2021 to 08/30/2022 in the subspecialties of virology, syphilis serology, general immunology, and ABO and Rh testing. Findings include: 1. Review of the form Form CMS-116 signed and dated by the LD on 12/13/2022, found the hours of laboratory testing to be 24-hours per day, 7-days per week. 2. Review of the 2021 and the 2022 weekly staff responsibilities spreadsheets revealed the following statements: Week of October 4th - "sink or swim" Week of October 11th - "sink or swim" Week of November 15th - "sink or swim" Week of November 29th - "pray we get travel tech" Week of January 3rd - "pray for travel tech" 3. Reviews of training records revealed the following: Month/Year Number of Trained TP April 2021 2 May 2021 4 June 2021 4 July 2021 4 August 2021 4 December 2021 4 January 2022 3 February 2022 2 March 2022 2 April 2022 4 May 2022 3 June 2022 2 July 2022 2 August 2022 3 4. An interview with GS #3 on the day of the inspection at 1:00 PM confirmed the laboratory was experiencing a "high rate of turn-over with testing personnel". 5. An email received 01 /31/2023 at 5:18 PM from GS #1 stated the laboratory adjusted the hours of testing from 05/23/2022 to 01/08/2023 due to lack of testing personnel.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record reviews and an interview with General Supervisor (GS) #3, the laboratory failed to ensure GS #4, GS #5, and GS #9 met the minimum qualification requirements of 493.1461 to provide general supervision in accordance with 493.1463 in the subspecialties of virology, general immunology, ABO, and Rh testing from 02 /24/2021 through 01/30/2023. Findings Include: 1. The laboratory failed to ensure GS #4, GS #5, and GS #9 met the minimum qualification requirements of 493.1461 in the subspecialties of virology, general immunology, ABO, and Rh testing. (Refer to D6143)
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor

must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on record reviews and an interview with General Supervisor (GS) #3, the laboratory failed to ensure three out of nine GS met the appropriate qualification requirements under 493.1461 for high complexity testing. This deficient practice had

	the potential to affect 7,062 patients tested in the subspecialties of virology, general immunology, ABO, and Rh testing from 02/24/2021 through 01/30/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 01/31/2023, revealed three out of nine individuals listed and certified by the Laboratory Director to fulfill the position and responsibilities of a GS for the high complexity virology, general immunology, and ABO, and Rh testing procedures performed. 2. The inspector requested education documents from GS #3 for all GS listed on the Form CMS-209. 3. GS #3 was unable to provide the requested education documents for GS #4, GS #5, and GS #9. The interview occurred on 01/30 /2023 at 11:10 AM.
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 record reviews and an interview with General Supervisor (GS) #3, the laboratory failed to ensure TP#8, TP #9, TP #10, TP #11, TP #12, TP #13, TP #16, TP #18, TP #23, TP #28, TP #29, TP #30, TP #31, TP #32, TP #33, TP #34, TP #35, TP #36, TP #37, TP #38, and TP #39 met the minimum qualification requirements of 493.1489. This deficient practice had the potential to affect 7,062 patients tested in the subspecialties of virology, general immunology, ABO, and Rh testing from 02/24 /2021 through 01/30/2023. Findings Include: 1. The laboratory failed to ensure TP#8, TP #9, TP #10, TP #11, TP #12, TP #13, TP #16, TP #18, TP #23, TP #28, TP #29, TP #30, TP #31, TP #32, TP #33, TP #34, TP #35, TP #36, TP #37, TP #38, and TP #39 met the minimum requirements for high complexity testing personnel qualifications. (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 record reviews and an interview with General Supervisor (GS) #3, the laboratory failed to ensure 21 out of 39 Testing Personnel (TP) met the appropriate qualification requirements under 493.1489 for high complexity testing. This deficient practice had the potential to affect 7,062 patients tested in the subspecialties of virology, general immunology, ABO, and Rh testing from 02/24/2021 through 01/30/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 01/31/2023, revealed 21 out of 39 individuals listed and certified by the Laboratory Director to fulfill the position and responsibilities of a TP for the high complexity virology, general immunology, and ABO and Rh testing procedures performed. 2. The inspector requested education documents from GS #3 for all TP listed on the Form CMS-209. 3. GS #3 was unable to provide the requested education documents for TP#8, TP #9, TP #10, TP #11, TP #12, TP #13, TP #16, TP #18, TP #23, TP #28, TP #29, TP #30, TP #31, TP #32, TP #33, TP #34, TP #35, TP #36, TP #37, TP #38, and TP #39. The interview occurred on 01/30/2023 at 11:10 AM.