Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0335934	10/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Preterm	12000 Shaker Boulevard 4th Floor, Cleveland, 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
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interviews with Technical Consultant (TC) #2, the Laboratory Director failed to ensure the laboratory's quality assessment program was maintained to assure the quality of all patient testing procedures performed in the specialty of Hematology. This deficient practice had the potential to affect 8802 out of 8802 patient tests performed 6/1/2022 through 06/06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, signed by the Laboratory Director on 10 /04/2023 and on the amended Form CMS-209 on 10/06/2023, found two individuals, to include the Laboratory Director, qualified and listed to function as a TC. 2. Review of the laboratory's "Preterm Quality Assessment Plan" policy and procedure, provided on the date of the inspection, found the following statement: "The laboratory consultant...will perform a Quality Assurance Review quarterly." 3. Review of the laboratory's 2022 and 2023 "Quality Assurance Review" worksheets revealed incomplete quality assurance reviews on 09/07/2022, 12/21/2022, 03/15/2023 and 06 /06/2023. 4. The Inspector requested the laboratory's completed quality assessment documentation from 09/07/2022 through 06/06/2023 from TC#2. TC#2 stated they retired on 06/30/2022 and returned on 09/14/2023 on an interim basis until the laboratory hired another qualified TC. TC#2 confirmed that the Laboratory Director (TC#1) did not conduct and document all of the quality assessment activities since they separated employment from this facility in 2022 and returned in 2023 and was

	unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/05/2023 at 10:05 AM.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and an interview with Technical Consultant (TC) #2, the TC failed to evaluate and document semi-annual competency of Testing Personnel (TP) #4, TP#6 and TP#8 who were responsible for moderate complexity ABO Rh testing procedures during the first year the individuals tested patient specimens. This deficient practice had the potential to affect 7545 out of 7545 patient testing performed by three out of nine TP between 07/19/2022 through 12/31/2022. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 10/04/2023 and the amended Form CMS-209 on 10/06/2023, revealed nine individuals qualified and listed as TP. 2. Review of the laboratory's "Preterm Laboratory Quality Assessment Plan" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 07/22/2015, found the following statement: "6. All laboratory personnel's competency will be reviewed semi-annually in their first year...by the laboratory consultant." 3. Review of the laboratory's 2021, 2022 and 2023 competency assessment records, provided for the inspection, did not find any record of the following semi-annual competency assessments during the TP's first year of ABO Rh testing on patient specimens: Initial 6 month 12 month TP#4 07/26 /22 not done 09/26/23 TP#6 10/23/21 04/29/22 not done (separated employment 12/31 /2022) TP#8 01/19/22 not done n/a (separated employment 10/26/2022) 4. The Inspector requested the laboratory's semiannual competency assessment records for TP#4, TP#6 and TP#8, as indicated above from TC#2. TC#2 confirmed the TC did not assess the semiannual competency of TP#4, TP#6 and TP#8 during their first year of testing patient specimens according to the laboratory's policy and procedure and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/05/2023 at 9:45 AM.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and an interview with Technical Consultant (TC) #2, the TC failed to evaluate and document the annual competency of Testing Personnel (TP) #7 in 2021, TP#1, TP#2, TP#5 and TP#7 in 2022, and TP#5 in 2023 who were responsible for moderate complexity ABO Rh testing procedures for more than one year after the individuals began testing patient specimens. This deficient practice had the potential to affect 8802 out of 8022 patient testing performed by four out of nine

	TP between 2021, 2022 and 2023 to the date of the inspection. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 10/04/2023 and the amended Form CMS-209 on 10/06/2023, revealed nine individuals qualified and listed as TP. 2. Review of the laboratory's "Preterm Laboratory Quality Assessment Plan" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 07/22/2015, found the following statement: "6. All laboratory personnel's competency will be reviewed... annually thereafter by the laboratory consultant." 3. Review of the laboratory's "Laboratory Personnel Training and Competency Assessment Policy", provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 07/22/2015, found the following statement: "3)...and annually thereafter, the Laboratory Technical Consultant will review the personnel's competency..." 4. Review of the laboratory's 2020, 2021, 2022 and 2023 annual competency assessment records, provided for the inspection, did not find any record of the following annual competency assessments for ABO Rh testing on patient specimens: 2020 2021 2022 2023 TP#1 11/17/21 not done 09/26/23 TP#2 11/17/21 not done 09/26/23 TP#5 11/17/21 not done n/a (separated employment 10/26/2022) TP#7 11/18/20 not done not done n/a (separated employment 01/21/2023) 5. The Inspector requested the laboratory's annual competency assessment records for TP#1, TP#2, TP#5 and TP#7, as indicated above from TC#2. TC#2 confirmed the TC did not assess the annual competency of TP#1, TP#2, TP#5 and TP#7 according to the laboratory's policies and procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/05/2023 at 9:45 AM.