

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0340488	(X3) Date Survey Completed 01/04/2023
Name of Provider or Supplier Summa Health Medical Group Oncology	Street Address, City, State 161 North Forge St, Suite 198, Akron, 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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interviews with Testing Personnel (TP) #1 and the Office Manager (OM), the laboratory failed to ensure Technical Consultant (TC) qualification requirements of 493.1411 of this subpart were met. This deficient practice had the potential to affect 150,002 patients tested in the specialty of Hematology in this laboratory between 01/01/2021 and 12/31/2022. Findings Include: 1. The laboratory failed to ensure one out of two individuals listed on the CMS-209 and credentialed by the Laboratory Director (LD) met the TC qualification requirements. This individual provided technical consultation for the moderately complex complete blood count (CBC) and automated differential (Adiff) testing procedures performed. (Refer to D6034) 2. The TC failed to evaluate and document the competency of three out of three TP in 2021 and 2022 assuring their competency was maintained in order to perform moderately complex CBC and Adiff testing in the Specialty of Hematology and report the test results promptly, accurately, and proficiently. (Refer to D6046)</p>
D6034	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate</p>

complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interviews with Testing Personnel (TP) #1 and the Office Manager (OM), the laboratory failed to ensure one out of two individuals listed on the CMS-209 and credentialed by the Laboratory Director (LD) met the TC qualification requirements. This individual provided technical consultation for the moderately complex complete blood count (CBC) and automated differential (Adiff) testing procedures performed. This deficient practice had the potential to affect 88,506 patient CBC and Adiff testing conducted between 10/25/2021 and 01/04/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the LD on 01/04/2023, found two individuals, including the LD, listed and credentialed by the LD to perform the TC responsibilities for the moderately complex CBC and Adiff testing procedures performed. 2. Review of education records provided on the date of the inspection for TC#2 (aka, TP#1), revealed TC#2 achieved an Associate in Applied Science in Medical Laboratory Technology and an Associate of Arts in General Studies and did not meet the minimum TC qualification requirements. aka; also known as 3. Review of competency assessment documentation provided on the date of the inspection revealed an unqualified TC not employed in this laboratory anymore had assessed the competency of TP#1 on 12/03/2021. The unqualified TC#2 (aka,TP#1) then assessed the competencies of TP#2 on 05/10/2022 and TP#3 on 12/15/2022. 4. TC#2 (aka, TP#1) confirmed the highest level of education they achieved was an Associate in Applied Science in Medical Laboratory Technology and an Associate of Arts in General Studies, functioned in the roles and responsibilities of a TC and did not meet the minimum TC qualification requirements. The interview occurred on 01/04/2023 at 10:35 AM. 5. The OM confirmed neither the laboratory nor the laboratory's accrediting organization had identified the TP competency assessments were conducted by individuals who did not meet the CLIA TC qualification requirements throughout the past 30 plus years. The interview occurred on 01/04/2023 at 12:00 PM.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interviews with Testing Personnel (TP) #1 and the Office Manager (OM), a qualified Technical Consultant (TC) failed to evaluate and document the competency of three out of three Testing Personnel (TP) in 2021 and 2022 assuring their competency was maintained in order to perform moderately complex complete blood count (CBC) and automated differential (Adiff) testing in the specialty of Hematology and report the test results promptly, accurately, and proficiently. This deficient practice had the potential to affect 150,002 out of 150,002 patient CBC and Adiff tests conducted in 2021 and 2022. Findings Include: 1. Review of the laboratory's Form CMS-209 found two individuals, including the LD, listed, credentialed and approved by the LD via signature and date on 01/04/2023 to function in the roles and responsibilities as a TC, as well as three TP for the moderately

complex CBC and Adiff testing conducted. 2. Review of the laboratory's competency assessment documentation, provided for the inspection, identified the following dates and unqualified TCs who conducted TP competency assessments: I 6m 12m A21 A22 TP1 12/21,TC* nd nd n/a n/a TP2 n/a n/a n/a 07/21,TC* 05/22,TC2 TP3 12/22,TC2 n/a n/a n/a n/a I; initial 6m; 6 month 12m; month A21; annual 2021 A22; annual 2022 TC*; unqualified TC not employed anymore TC2; unqualified TC currently employed nd; not done n/a; not applicable 3. TP#1 confirmed the highest level of education they achieved was an Associate in Applied Science in Medical Laboratory Technology and an Associate of Arts in General Studies, functioned in the roles and responsibilities of a TC, assessed the competency of TP#2 and TP#3 in 2022 and did not meet the minimum TC qualification requirements. The interview occurred on 01/04/2023 at 10:35 AM. 4. The OM confirmed neither the laboratory nor the laboratory's accrediting organization had identified the TP competency assessments were conducted by individuals who did not meet the CLIA TC qualification requirements throughout the past 30 plus years. The interview occurred on 01/04/2023 at 12:00 PM.