

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2089250	(X3) Date Survey Completed 04/23/2019
Name of Provider or Supplier Children's Physicians - Council Bluffs	Street Address, City, State 1022 Woodbury Avenue, Council Bluffs, IA	
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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Sysmex XP-300 hematology procedure, Sysmex XP-300 analyzer printouts, patient test reports, quality assessment records and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/23/2019, the laboratory failed to establish a written quality assessment policy to monitor, assess, and correct problems related to entering the incorrect medical record number into the Sysmex XP-300 hematology analyzer for three out of three patients in January of 2019. The findings include: 1. The Sysmex XP-300 hematology procedure stated, as part of performing a complete blood cell count (CBC), the testing personnel must "Enter the MRN [medical record number] using the touch keypad." 2. Patient A (identifier MRN XXXX014) had a CBC performed on 1/12/2019. The Sysmex XP-300 printout had the MRN as XXXX015. 3. Patient B (identifier MRN XXXX159) had a CBC performed on 1/23/2019. The Sysmex XP-300 printout had the MRN as 2. 4. Patient C (identifier, MRN XXXX519) had a CBC performed on 1/27/2019. The Sysmex XP-300 printout had the MRN as XXXX520. 5. Quality assessment activities performed in January 2019 did not identify problems related to entering the incorrect medical record number into the Sysmex XP-300 hematology analyzer.</p>