

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1015261	(X3) Date Survey Completed 04/12/2023
Name of Provider or Supplier Kings Daughter's Medical Center	Street Address, City, State 916 11th Street, Portsmouth, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure policies and procedures were approved, signed and dated before use. This deficient practice had the potential to affect 23,240 patients tested under the specialties of Hematology and Chemistry from 06/01/2021 to 08/09/2021. Findings Include: 1. An email submitted on 04/05/2023 at 3:51 PM from the TC stated a new LD had assumed the role on 06/01/2021 but the laboratory had not submitted a Form CMS-116 notifying CMS of the change. 2. Review of the laboratory's "General Procedure Manual" table of contents provided on 04/11/2023 via electronic mail (email) revealed an LD approval signature and date of 08/09/2021. 3. During a telephone interview on 04/12/2023 at 11:20 AM, the TC confirmed policies and procedures were not approved, signed and dated by the new LD before use.</p>