Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453069	10/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Decatur Health System Inc	810 W Columbia St, Oberlin, KS	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the review of proficiency testing (PT) records from American Proficiency Institute (API), the laboratory failed to successfully participate in PT for the analyte: unexpected antibody detection for two out of three consecutive proficiency testing events: 2020 Event 3 and 2021 Event 2 (refer to D2172).
D2172	UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(e) Failure to achieve an overall testing event score of satisfactory for two consecutive

	testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: A PT desk review and phone interview on 10/19/21 revealed the laboratory failed to successfully particiate in PT from API for unexpected antibody detection. Findings: 1. Review of the 2020 API 3rd Event revealed a score of 0% for unexpected antibody detection. 2. Review of the 2021 API 2nd Event revealed a score of 60% for unexpected antibody detection. 3. Phone interview 10/19/21 at 10:10 a.m. with the general supervisor confirmed, the laboratory failed to successfully particiate in PT from API for unexpected antibody detection.