Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2137525	05/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Prevea Health Mondovi	250 State Road 37, Mondovi, WI	

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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not retain validation records for one of two i-STAT analyzers the laboratory used since starting non-waived testing in May 2022. Findings include: 1. Review of laboratory records showed the laboratory started non-waived testing in May 2022 including testing with an iSTAT analyzer. Further review showed the laboratory validated a new i-STAT analyzer in November 2022 and discontinued the use of the first analyzer. No records of the laboratory's validation of test system performance for the i-STAT analyzer used from May to November 2022 were available. 2. Interview with the technical consultant on May 4, 2023 at 11:30 AM confirmed the laboratory had not retained the records of the validation for the i-STAT analyzer used by the laboratory from May - November 2022 for at least two years.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records, observation of slides in the laboratory, and interview with testing personnel, the laboratory has not documented the reactivity of the Camco Quik Stain on days of use for hematology staining for seven patients in the last six months. Findings include: 1. Review of hematology procedures showed no requirement for testing personnel to document the reactivity of the Camco Quik Stain used for staining hematology slides for microscopic examination. 2. Review of laboratory records from 2022 and 2023 showed no documentation of the reactivity of the hematology Camco Quik Stain. 3. Observation of stained slides in the laboratory on May 4, 2023 at 11:30 AM showed testing personnel retained seven stained hematology slides. 4. Interview with testing personnel (staff A) on May 4, 2023 at 11:30 AM revealed personnel had not documented the reactivity of the Camco Quik Stain each day of use for hematology slide staining. Further interview revealed the laboratory retains stained slides for six months after testing.