Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1017876	04/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
U A M S Cytogenetics	5800 West 10th Street, Suite 200, Little Rock, AR	

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
D0000	An onsite validation survey was conducted on 04/02/2026, and standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy/procedures, the General Supervisor's (GS) annual competency form, and an interview with the GS, the laboratory failed to have a policy or procedure to assess the competency for 1 of 1 GS. Findings Include: a. The laboratory was asked to provide a policy or procedure that stated the frequency and steps for the competency assessment of the GS based on the duties the laboratory director delegated. No policy or procedure was provided. b. The review of the "LPSL Annual Leadership Competency-Supervisor" for the GS competency revealed that the signed "Assessor" (signed 01/16/2026) and "CLIA Director" (signed 02/03/2026) were not listed on the CMS-209. c. On 04/02/2026 at 9:59 AM in the office, an interview with the GS, as listed on the CMS-209, stated competency was performed annually, and confirmed the signed Assessor and CLIA Director were not listed on the CMS-209.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and,

	when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies/procedures and an interview with the General Supervisor, the laboratory failed to define the temperature range for specimen storage and transport for 5 of 5 specimen types. Findings Include: a. A review of the laboratory's online "General Collection Policy" revealed "Transport and Delivery to Lab ...Deliver specimens the day of collection at room temperature ...Specimens should be transported at room temperature. Do not freeze or send samples on ice. Specimens collected after hours should be kept at room temperature ..." and "Sub-optimal or Unacceptable Specimens ...Solid Tissue and Tumor ...Received more than 24 hours after collection if not refrigerated, or 48 hours after collection if refrigerated". The room and refrigerated temperature range were not defined. b. A review of the laboratory's policy "GC.A21 Specimen Collection", approved by the Laboratory Director on 10/23/2025, revealed that "Specimens collected after hours should be kept at room temperature, except for solid tissue specimens, which, if not received on the day collected, should be refrigerated to inhibit potential bacterial growth". Additional information by specimen types included: 1. Peripheral blood and leukemic blood, bone marrow and fine needle aspirates-"Deliver specimens the same day at room temperature ...Specimens should be transported at room temperature." 2. Pleural effusion and ascites fluid, cerebrospinal fluid, tissue samples-"Specimens should be transported at room temperature." 3. Solid tumors and lymph nodes-"Specimens should be transported at room temperature ...Specimens collected after hours should be kept at room temperature ..." The room temperature range was not defined. c. A review of the "Cytogenetics Requisition" revealed "Solid Tissue ...If same day delivery is not possible, refrigerate overnight." A refrigerated temperature range was not defined. d. The instructions for solid tissue storage were inconsistent with the Specimen Collection procedure, the General Collection Policy, and the Cytogenetics Requisition. e. On 04/02/2026 at 10:25 AM in the office, an interview with the General Supervisor, as listed on the CMS-209, confirmed that the temperature range was not defined, the temperature is not monitored during transport, and when samples are received, staff confirmed the temperature visually and by touch. f. The laboratory performs 2,300 clinical cytogenetics tests per year.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Stain Reactivity Log, the laboratory's policy /procedures, and an interview with the General Supervisor, the laboratory failed to define staining characteristics for 1 of 1 slide stain. Findings Include: a. A review of the Stain Reactivity Log revealed that the stain quality was documented as "Pass" or "Fail". b. A review of the laboratory's policy "CG.T03 Trypsin-Giemsa Banding" approved by the Laboratory Director on 10/23/2025, revealed no information on evaluating stain quality. The laboratory was asked to provide a policy or procedure

	describing the staining characteristics used to determine "Pass" or "Fail," but no documentation was provided. c. On 04/02/2026 at 10:46 AM in the office, the General Supervisor, as listed on the CMS-209, was able to describe a quality stain, but confirmed the procedures did not define the staining characteristics used to determine "Pass" or "Fail".
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures and media verification form, the laboratory failed to define results for new batches of laboratory-prepared media for 1 of 1 media types. Findings Include: a. A review of the laboratory's procedure "CG. A12 Quality control of Media and Regents", approved by the Laboratory Director on 10/23/2025, revealed "The harvested specimen from the new media is compared to the same patient specimen cultured in the old media for absence of microbial contamination and for similar level of mitotic index to verify both sterility and sufficient ability to support growth." b. A review of the "Cytogenetics Laboratory Media Verification Form" for RPMI (Roswell Park Memorial Institute) media signed by the General Supervisor 09/10/2025 revealed the contamination status and comparison of the mitotic index was recorded as "Pass" or "Fail." c. The procedure did not define the characteristics used to determine the "Pass" or "Fail".
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, the Laboratory Director (LD) failed to provide oversight of the laboratory's overall operations and administration. Findings Include: a. The LD failed to ensure the General Supervisor's competence was assessed by qualified laboratory personnel. Refer to D5209. b. A

	review of the laboratory's policy "CG.A03 Laboratory Director's Duties" revealed, "During any absence of the Cytogenetics lab director, the director's duties will be performed by the director of [Name of different CLIA laboratory]."