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D2000	493.801 ENROLLMENT AND TESTING OF SAMPLES Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. This CONDITION is not met as evidenced by: Based on record review of 2009 immunohematology proficiency testing records (three events) and an interview with the technical consultant on 2/8/10, the laboratory failed to ensure that proficiency testing specimens were tested in the same manner as patient specimens following the criteria in subpart H of this part. Findings include: Refer to: D2010: The laboratory failed to test proficiency testing samples in the same manner as patient specimens. D2015: The laboratory failed to ensure that attestation statements were signed by the testing personnel and the laboratory director or designee.	D2000		2/26/10
D2010	493.801(b)(2) TESTING OF PROFICIENCY SAMPLES The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by:	D2010		2/26/10

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 03/02/2010

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D2010	Continued From page 1 Based on record review of 2009 immunohematology proficiency testing records (three events) and an interview with the technical consultant on 2/8/10, the laboratory failed to ensure that proficiency testing specimens were tested in the same manner and patient specimens. Findings include: On 2/8/10 the surveyor reviewed the proficiency testing records for three events in 2009. The records indicated the following: --First event: two individuals tested specimen 1, two individuals tested specimen 2, two individuals tested specimen 3. --Second event: two individuals tested specimen 1, two individuals tested specimen 3. --Third event: two individuals tested specimen 1. The technical consultant confirmed that the more than one individual did test the same specimen prior to reporting the results to the proficiency testing provider.	D2010		
D2015	THIS IS A REPEAT DEFICIENCY 493.801(b)(5)(6) TESTING OF PROFICIENCY SAMPLES The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the	D2015		2/26/10

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D2015	Continued From page 2 same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review of 2009 immunohematology proficiency testing records (three events) and an interview with the technical consultant on 2/8/10, the laboratory failed to ensure that the attestation statements were signed by the analysts who performed the testing and the laboratory director documenting that proficiency testing samples were tested in the same manner as patient specimens. Findings include: On 2/8/10 the surveyor reviewed the test records and attestation records for three 2009 immunohematology proficiency testing events. Two out of three of the attestation statements indicated that one testing person performed all the testing although the test records indicated that multiple testing personnel had performed the testing. Also the attestation statements for three of the events were not signed by the laboratory director or designee.	D2015		
D5217 120M 130M	493.1236(c)(1) EVALUATION OF PROFICIENCY TESTING PERFORMANCE At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and an interview with the	D5217		2/26/10

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D5217	Continued From page 3 technical consultant on 2/8/10, the laboratory failed to ensure that at least twice annually the laboratory verified the accuracy of vaginal wet mounts and KOH preps. Findings include: On 2/8/2010 the technical consultant confirmed that the laboratory did not verify the accuracy of vaginal wet mounts and KOH preps at least twice annually. The laboratory performs 50 wet preps and 50 KOH preps annually.	D5217		
D6000	493.1403 LABORATORY DIRECTOR The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the technical consultant on 2/8/10, the laboratory director did not provide overall management and direction in accordance with 493.1407. Findings include: -Refer to D6014: The laboratory director failed to ensure that personnel are performing test methods as required for accurate and reliable results. -Refer to D6016: The laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H of this part. -Refer to D6018: The laboratory director failed to ensure that proficiency testing reports were	D6000		2/26/10

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D6000	Continued From page 4 reviewed. -Refer to D6020: The laboratory director failed to ensure that the quality control program was maintained. -Refer to D6031: The laboratory director failed to include a venipuncture procedure in the procedure manual. -Refer to D6032: The laboratory director failed to provide a job description for the technical consultant.	D6000		
D6014	493.1407(e)(3)(iii) DIRECTOR RESPONSIBILITIES The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review of hemoglobin testing and Rh typing and interviews with one testing person and the technical consultant on 2/8/2010 and 2/9/2010, the laboratory director failed to ensure that laboratory personnel were performing the test methods as required for accurate and reliable results. Findings revealed: Hemoglobin Testing: The laboratory performed hemoglobin testing using a HemoCue instrument. The testing personnel were required to test a low control and high control daily prior to patient testing. The surveyor reviewed quality control records for 2009 and 2010. A random sampling of results	D6014		2/26/10

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D6014	Continued From page 5	D6014		

indicated the following:
--From July 2009 through February 2010 six hundred ninety-five patients (approximately 33 %) were tested on days when the low control was out of range.
--On July 9, 11, 14, and 17 2009 neither the low or the high control were run. Fifty-five patients were tested.

The laboratory policy for hemoglobin testing stated: "Retest all levels lower than 10 g/gl or below." A random review of patient test logs indicated that patient testing was not repeated on the following hemoglobin results: 1/5/10 Patient A 9.2 gm/dl, 1/9/10 Patient B 9.9 gm/dl, 1/7/10 Patient C 6.3 gm/dl, a/7/10 Patient D 9.5 gm/dl, 8/15/09 Patient E 8.7 gm/dl, 8/18/09 Patient F 8.4 gm/dl, 1/19/10 Patient C 8.2 gm/dl.

Rh Typing:

The laboratory performed Rh typing. The manufacturer's instructions state that the slide be pre-warmed on an Rh view box. One drop of Anti-D is added to the slide. Next two drops of whole blood is added to the slide. The blood and Anti D are mixed with an applicator stick. The slide is tilted back and forth for two minutes. Agglutination indicates a positive test. No agglutination indicates a negative test.

On 2/9/2010 the surveyor observed one testing personnel perform the typing. The testing personnel did not use a timer to determine the end point of the test. The testing person did not tilt the slide back and forth as indicated from the manufacturer's instructions.

A random review of quality control records

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D6014	Continued From page 6 indicated that there was no documentation of the temperature of the Rh viewbox from January 1, 2010 through February 9, 2010. The manufacturer stated that the temperature of the box must be between 40 and 50 degrees centigrade. The laboratory performs 2085 Rh typings annually.	D6014		
D6016	493.1407(e)(4)(i) DIRECTOR RESPONSIBILITIES The laboratory director must ensure that proficiency testing samples are tested as required under Subpart H of this part. This STANDARD is not met as evidenced by: Based on record review of 2009 immunohematology proficiency testing records (three events) and an interview with the technical consultant on 2/8/10, the laboratory director failed to ensure that proficiency testing specimens were tested as required under Subpart H of this part. Findings include: On 2/8/10 the surveyor reviewed the proficiency testing records for three events in 2009. The records indicated the following: --First event: two individuals tested specimen 1, two individuals tested specimen 2, two individuals tested specimen 3. --Second event: two individuals tested specimen 1, two individuals tested specimen 3. --Third event: two individuals tested specimen 1 Refer to D2010 On 2/8/10 the surveyor reviewed the test records	D6016		3/2/10

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D6016	Continued From page 7 and attestation records for three 2009 immunohematology proficiency testing events. Two out of three of the attestation statements indicated that one testing person performed all the testing although the test records indicated that multiple testing personnel had performed the testing. Also the attestation statements for three of the events were not signed by the laboratory director or designee. Refer to D2015	D6016		
D6018	493.1407(e)(4)(iii) DIRECTOR RESPONSIBILITIES The laboratory director must ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review of 2009 immunohematology proficiency testing records (three events) and an interview with the technical consultant on 2/8/10, the laboratory director failed to ensure that proficiency testing reports were reviewed by the appropriate staff. Findings include: The 2009 proficiency testing results did not include documentation that the laboratory director or designee had reviewed the results.	D6018		3/2/10
D6020	493.1407(e)(5) DIRECTOR RESPONSIBILITIES The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided.	D6020		3/2/10

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D6020	Continued From page 8 This STANDARD is not met as evidenced by: Based on record review and an interview with one testing person and the technical consultant on 2/8/2010 and 2/9/2010, the laboratory director failed to ensure that the quality control program was maintained. Findings include: A review of daily test logs that included quality control documentation for the HemoCue and Rh typings by the surveyor determined that testing personnel were not performing quality control appropriately. Furthermore the logs for all of 2009 and 2010 did not include documentation of review by the laboratory director or the technical consultant.	D6020		
D6031	493.1407(e)(13) DIRECTOR RESPONSIBILITIES The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on procedure manual review and an interview with one testing person on 2/9/2010, the laboratory director failed to ensure that a venipuncture procedure was available to testing personnel. Findings include: An interview with one testing person on 2/9/2010 confirmed that the laboratory drew blood specimens for send out to a reference laboratory. The testing person was not able to state the accurate order of draw for Vacutainer tubes. Furthermore the testing person did not know how to collect a prothrombin tube using a butterfly collection system.	D6031		3/2/10

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D6031	Continued From page 9 A review of the laboratory procedure manual by the surveyor confirmed that the laboratory director had not provided a venipuncture procedure to testing personnel.	D6031		
D6032	493.1407(e)(14) DIRECTOR RESPONSIBILITIES The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on procedure manual review and an interview with the technical consultant on 2/8/2010, the laboratory director failed to specify in writing the duties and responsibilities of the technical consultant. Finding include: On 2/8/2010 the surveyor asked the practice manager who signed off on all the testing personnel training and competency documents as the technical consultant for a written job description signed by the laboratory director. The practice manager was not able to provide the surveyor with a signed job description by the laboratory director. Furthermore the practice manager was not able to provide a job description for the laboratory director and the testing	D6032		3/2/10

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D6032	Continued From page 10 personnel that included responsibilities.	D6032		