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Memorandum

To: Leigh Anne Myers
FDA

From: Heather Nieman
Universal Reagents, Inc.

CC: Don Foster
Universal Reagents, Inc.

Date: June 7, 2002

Re: Response to issued 483

1. VIRAL MARKERS

In response to the questions you have posed regarding certain viral marker results, I have complied the following answers and written SOP 030.26 as an additional procedure for our viral marker system.

Of the units in question, there are two different scenarios. The first scenario concerns units 0729859, 0730860, 0730900, 0730911, and 0730912. In these instances, part of the results received from our testing center were misplaced and not in the viral marker binder. We were able to obtain back-up results from the testing center indicating that pages were missing. The page numbers on the fax identification header demonstrated this. Copies of these complete results are attached. We firmly believe that the phlebotomist reporting the results did indeed have the complete results at the time of reporting and that they were subsequently misplaced.

The second scenario concerns unit 0729718. This case is more complicated. In early May 2001, the current Director of Quality Assurance was terminated for non-performance. This individual was very disgruntled and threatened to retaliate. An EEOC complaint was filed and personnel files disappeared. There is evidence that the test results that included unit 0729718 were tampered with. All other results were signed off by the Phlebotomy Supervisor and placed in the viral marker binder a specific way. These results stood out. The Phlebotomy Supervisor did not sign them, the hole-punches were not consistent with the other results, the forms were in an incorrect order, and multiple removed staple punctures indicate a missing section. We obtained another copy of the repeat-test results from our testing center that show that the tests were done and the unit was non-reactive. The results are attached.

2. REACTIVE HBS

The initial lab results on unit 0731055 drawn 4/3/02 show reactive for HBsAg. However, a reactive is not necessarily a positive. A reactive indicated on lab results means that it was reactive for the first test. Any reactive is then automatically submitted to a twice-repeat same test the next day. If either of those tests is reactive, the results are returned to URI as 'P' for positive. URI did not receive a result of 'P' on this unit. Attached is the result from the twice-repeat same test done on 4/8/02 in which the unit is non-reactive.

3. WHOLE BLOOD DONATION FREQUENCY AND INFORMED CONSENT

To prevent whole blood donors from donating less that 56 days apart, SOP 020.32 and SOP 020.32A has been created as instructions and a sign-off form that needs to be filled out and signed off by a member of management with executive responsibility. At the time of this memo, the only authorized individuals to sign off are Heather Nieman and Don Foster. Copies of these new SOP's are attached.

4. TEMPERATURE GRAPHS

In response to questions regarding Freezer M's temperature range differing from the temperatures listed in SOP 100.01. The freezers are indeed kept at the correct temperature and SOP 100.01 has been revised to match the correct range.

I believe this answers all the questions that were brought to me throughout your investigation. If I have missed any or you have additional questions, I am more than happy to discover the answer.