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August 11, 2003

**Via Electronic Transmission**

Division of Dockets Management (HFA – 305)
Food and Drug Administration
5630 Fishers Lane, Rm. #1061
Rockville, MD 20852

Re: Request for a Hearing on Proposal to Revoke U.S. License No. 0887
Docket No. 2003N-0232

Dear Sir:

These objections and requests for a hearing are submitted by Universal Reagents, Inc. ("URI") in response to the October 23, 2003 FDA Form-483 ("Form-483"), wherein FDA proposes to revoke URI's U.S. License No. 0887.

## Introduction

The gravamen of the FDA's decision to revoke URI's license is that URI allegedly "willfully engaged in violative record keeping practices and provided false manufacturing records to FDA" and that URI's "June 7, 2002 response to FDA Form-483 demonstrate[d] that [URI] willfully continue[d] to submit falsified documents to FDA." Form-483 at p.3.

As discussed in more detail below, while URI does not deny that falsified documents were apparently created and submitted to the FDA, URI did NOT willfully or knowingly "engage in violative record keeping" and/or "submit falsified documents to the FDA." To the contrary, at the time the documents were submitted to the FDA, URI (including its management and all but one employee) did not know that there had been any falsification. However, based upon further inquiry by the FDA and additional URI investigation, URI now believes that the violative record keeping and falsification of records were the work of

The important point is that at the time of the FDA inspection and when the documents were submitted to the FDA on June 3 and June 7, URI was unaware of actions. left the employ of URI in early August 2002.

**Background**

FDA inspectors conducted an on-site inspection at URI from Wednesday, May 29 through Friday, May 31. URI and its staff cooperated completely with the FDA during its investigation. At the end of the three-day, on-site inspection, the FDA personnel identified documentation problems with regard to five plasma units. In particular, according to the FDA inspector's review, there were missing documents for the Hepatitis B and/or HIV tests for the following units: 0730900, 0730911, 0730912, 0729859, and 0729718. When the FDA inspectors left URI at approximately 12 noon on Friday May 31, 2002, URI representatives, including Heather Nieman, indicated that they would make a more exhaustive search for the missing documentation and try to have it to the FDA investigators by Monday June 3, 2002.

URI was confused about why the documents were missing. According to its contract with CIRBC (the testing laboratory used by URI for Hepatitis B and HIV tests, also known as IBC and/or the Indiana Blood Bank), CIRBC should have alerted URI that the tests were not performed. See URI/CIRBC Contract at part II, A, 6., attached hereto as **Exhibit A**. URI has never found documentation from CIRBC indicating that the requested tests were not performed.

On Saturday June 1, 2002, worked with representatives of CIRBC to search for the missing test documentation. met with several CIRBC representatives on Saturday, June 1 at different times during the day in an effort to obtain the missing documentation. See 7/23/02 Statement of attached hereto as **Exhibit B**. According to , she ultimately obtained the missing documentation from a CIRBC representative late in the day. returned to URI at about 9:00 p.m. on Saturday, June 1 and placed the missing documents in the chair of Kenneth Springer, URI Director of Customer Service.

On Sunday, June 2, 2002, Heather Nieman went to her office at URI to begin writing a report about the efforts URI had made to locate the missing test data. Upon her arrival at URI, Ms. Nieman unexpectantly found what she thought were the missing documents on Ken Springer's chair. See 7/18/02 Statement of Heather Nieman attached hereto as **Exhibit C**. Ms. Nieman assembled the documents for submission to the FDA on Monday, June 3.

When Mr. Springer reported to work on Monday morning June 3, 2002, he found the documents left by . Mr. Springer quickly reviewed the documents and determined that they were the documents that FDA investigators were seeking and, as is

company practice, he initialed and dated the documents at the bottom. Ultimately, the documents were faxed to FDA Inspector Leigh Anne Myers that day. It is important to understand that Mr. Springer did not review the documents is detail; he merely initialed and dated the documents. Mr. Springer then passed the documents on to Ms. Nieman for submission to the FDA. also initialed and dated the documents on June 3, 2002.

Ms. Nieman, unaware of the falsification, forwarded the documents to Ms. Myers at the FDA on Monday, June 3. On June 7, 2002, in response to additional questions by Ms. Myers. Ms. Nieman sent a follow-up memo describing URI's internal investigation. See June 7, 2002 Memo from Heather Nieman to Leigh Anne Myers attached hereto as **Exhibit D**. As Ms. Nieman explained in her memo to Ms. Myers, as of June 7, URI was still not aware of actions. While URI was now aware that documents had been altered, URI believed, based upon the fax legends and fonts of the various documents, that the alterations did not occur at URI.

Following the FDA inspection and URI's June 3 and June 7 submissions, FDA investigators returned to URI on or about June 17, 2002 for additional investigation. The FDA investigators, Leigh Anne Myers and Kag Gagnoni (with the FDA Office of Criminal Investigation) met with URI personnel and reviewed additional documents. URI cooperated fully and completely with Ms. Myers and Mr. Cagnoni in an effort to discover what happened. See 7/30/02 Statement of Ken Springer attached hereto as **Exhibit E**.

Based upon the July 17, 2002 FDA investigation a more intensive inquiry, URI has determined that false documents were in fact created and submitted to the FDA, including documents that were submitted on June 3 and June 7, 2002, after the on-site FDA investigation of URI. Moreover, URI now believes that was involved in the falsification process and, further, that the falsification did not take place at URI or on its computers. As explained below, the markings on the documents in question, including their headings and fonts, demonstrate that the alteration was done somewhere else. More importantly for present purposes, and contrary to the FDA's contention in the Form-483, URI did not willfully falsify and/or submit false documents to the FDA; rather, URI was unaware of the falsification at the time.

In addition, URI has instituted new procedures to avoid such fraud in the future. A copy of the new procedure is attached hereto as **Exhibit F**. According to these new procedures, all plasma units are quarantined until URI checks and double-checks that the necessary testing has been performed. URI also provides copies of the complete testing history to a purchaser for any unit purchased.

**A. <u>FDA Finding No. 1</u>:**

In violation of Sec. Sec. 610.40(a) and 606.160(b)(2)(i), test results for Source Plasma units 0730900, 0730911, and 0730912 for the

hepatitis B surface antigen (HBsAg) and the antibody to the human immunodeficiency virus types 1 and 2 (anti-HIV-1/2) were missing from the Transfer PC Mainframe Unit Rejection Report (a computer generated report). On June 3, 2002, URI provided the FDA investigator with what URI identified as the missing test results. According to these results, the HBsAg and anti-HIV-1/2 tests, which purportedly were performed by CIRBC, were negative for Source Plasma units 0730900, 0730911, and 0730912. However, the document did not bear a date or time in the designated reporting fields. Contrary to the documents obtained at the URI inspection, FDA's inspection of CIRBC disclosed that the required testing for HBsAg and anti-HIV-1/2 was not completed or performed for these Source Plasma units.

**URI Objections to FDA Finding No. 1:**

URI objects to FDA Finding No. 1 to the extent the FDA contends that URI willfully falsified documents and knowingly submitted those documents to the FDA.

First, the FDA rightly contends that Hepatitis B and HIV test results were missing in URI files for units 0730900, 0730911 and 0730912. Attached hereto as **Exhibits 1-A**, **1-B** and **1-C** are copies of test reports from CIRBC clearly showing that there were no test results for Hepatitis B and HIV for those three units. These three documents were in URI's files and were not hidden from the FDA investigators. Second, attached hereto as **Exhibit 1-D** is the falsified document provided by on or about June 1, 2002. At the bottom of **Exhibit 1-D** are the initials of and the date she initialed it – "6-3-02." Upon closer examination, it is apparent that **Exhibit 1-D** has been altered to show that the test results for the three units in question for the Hepatitis B and HIV tests were actually performed and reported as "N" for non-responsive. **Exhibit 1-D** contains no date or time. Mr. Springer did not review this document in detail when he found it on his chair on June 3, 2002 and merely initialed it and sent it on to Ms. Nieman to be forwarded to the FDA investigators.

It is important to understand that after learning of the apparent falsification, URI immediately quarantined the remaining units and notified a purchaser of two of the three units of the problem. URI had additional tests performed by a different laboratory to confirm that they were in fact non-responsive. On October 29, 2002, URI received test results from ZLB Laboratories in Miami, Florida for Hepatitis B and HIV tests upon units 0730900, 0730911 and 0730912; these new tests confirmed that each was in fact negative. A copy of those test results is attached hereto as **Exhibit 1-E**.

Units 0730900 and 0730911 were sold to Gradipore located in Sydney, Australia on April 19, 2002. On October 29, 2002, URI notified Gradipore via fax that units 0730900 and 0730911 has been retested and the results were negative. See URI correspondence with Gradipore attached hereto as **Exhibit 1-F**. A copy of the ZLB test

results were forwarded to Gradipore immediately after URI received these new test results.

Unit 0730912 has never been sold and remains at URI today.

**URI Request for a Hearing on Objections to FDA Finding No. 1:**
Pursuant to 21 CFR § 12.22, URI requests a hearing on each of the matters objected to above. At a hearing, URI will present the evidence and testimony discussed above to establish that URI did not willfully falsify documents and/or submit false documents to the FDA.

**B. FDA Finding No. 2:**

In violation of Sec. Sec. 610.40(a) and 606.160(b)(2)(i), HBsAg and anti-HIV-1/2 test results for Source Plasma unit 0729859 were missing on a Transfer Report and on a Testing Status Report. An additional notation on the Testing Status Report stated ``sample too old to complete testing." An additional record that FDA collected during the URI inspection, a Laboratory Request Form dated June 4, 2001, that URI generated, showed that all test results for unit 0729859, including HBsAg and anti-HIV-1/2 testing, were documented as ``NR" or non-reactive. During the closeout discussion on June 3, 2002, URI provided the FDA investigator with a Testing Status Report stating that the testing had been performed at CIRBC and that test results for HBsAg and anti-HIV-1/2 were ``N" or negative for unit 0729859. Contrary to the documents obtained at the URI inspection, FDA's inspection of CIRBC disclosed that infectious disease testing for HBsAg and anti-HIV-1/2 was not performed on Source Plasma unit 0729859.

**URI Objections to FDA Finding No. 2:**

URI objects to FDA Finding No. 2 to the extent that FDA contends that URI willfully falsified test results and knowingly submitted false documents to the FDA.

First, as the FDA inspectors discovered during their on-site inspection, there were no test results for the Hepatitis B and HIV tests for Unit 0729859. Attached hereto are copies of **Exhibits 2-A** and **2-B** which are test result forms from CIRBC to URI showing that there were no test results for unit 0729859 for either the Hepatitis B or HIV tests. In addition, attached as **Exhibit 2-C** is a copy of a "Testing Status Report" from CIRBC to URI also indicating that there were no test results for unit 0729859 for the Hepatitis B and HIV test. **Exhibit 2-C** has handwriting from CIRBC stating "sample too old to complete testing." These three documents, **Exhibits 2-A**, **2-B**, and **2-C**, were all in URI's records and available for FDA inspectors during their on-site inspection.

**Exhibit 2-D** is a copy of a falsified "Testing Status Report" purportedly showing the test results for Hepatitis B and HIV for unit 0729859 to be "N" for non- responsive. This document was provided to URI by on June 1, 2002. Like the previous false document, the bottom of this document contains the initials of with a date of 6-3-02. Again, as explained above Mr. Springer did not review this document in detail; he merely initialed it and passed it on so it could be faxed to the FDA.

The FDA incorrectly states in Finding No. 2 that an "additional record that FDA collected during the URI inspection, a Laboratory Request Form dated June 4, 2001, that URI generated, showed that all test results for unit 0729859, including [Hepatitis B] and [HIV] testing, were documented as 'NR' or 'non reactive.'" This statement is inaccurate. URI does not have a "Test Request Form" for sample 0729859 dated June 4, 2001. Instead, attached hereto as **Exhibit 2-E** is a "test request form" dated May 4, 2001. In addition, **Exhibit 2-E** is a "Test Request Form", which means it is the document transmitted from URI to CIRBC **requesting** that certain tests be performed; it does not report test results. This form shows only that URI requested that certain tests be performed on certain units; contrary to FDA's contention, this document nowhere indicates that test results were "NR" or non-reactive.

Finally, it is important to note that, like the three prior units, when URI discovered the discrepancy with unit 0729859, URI had the unit retested by ZLB Labs and the results were non-reactive for both Hepatitis B and HIV. A copy of those test results are attached as **Exhibit 2-F**. Moreover, when URI discovered the problem, it immediately quarantined the unit and it has never been shipped to any customer. Unit 0729859 is still in URI storage.

**URI Request for a Hearing on Objections to FDA Finding No. 2:**
Pursuant to 21 CFR § 12.22, URI requests a hearing on each of the matters objected to above. At a hearing, URI will present the evidence and testimony discussed above to establish that URI did not willfully falsify documents and/or submit false documents to the FDA.

**C. FDA Finding No. 3:**

In violation of Sec. 606.160(b)(2)(i), URI failed to maintain anti-HIV-1/2 re-testing results for Source Plasma unit 0729718. On a Transfer Report dated May 5, 2001, Source Plasma unit 0729718 tested reactive for anti-HIV-1/2 in testing conducted by CIRBC. Rather than producing the results of re-testing on that unit, however, URI provided the FDA investigator, during the closeout discussion on June 3, 2002, with a Testing Status Report for unit 0729718 that noted an ``N'' or ``non-reactive'' test result for the initial anti-HIV-1/2 test. No date or time was documented on the report; however, a notation on the report stated that it was reviewed by URI on May 9, 2000 [sic]. The sequence number noted on the report was 7899. FDA's inspection of CIRBC

disclosed that all infectious disease testing related to anti-HIV-1/2 that CIRBC performed on unit 0729718 in 2001 was associated with sequence number 1995, not 7899. CIRBC's records showed that anti-HIV-1/2 testing for unit 0729718 was performed on or about May 5, 2001, and the result was reactive. CIRBC's records showed that the results of repeat duplicate anti-HIV-1/2 tests on unit 0729718, conducted on May 7, 2001, were negative.

In a certified, return-receipt letter dated October 23, 2002, and issued under Sec. 601.5(b), FDA outlined the deviations noted at the inspection of URI. FDA notified URI of FDA's intent to revoke U.S. License No. 0887 and announced the agency's intent to offer an opportunity for hearing. In situations involving willfulness, FDA need not provide an opportunity for the licensee to demonstrate or achieve compliance. FDA acknowledged receipt of URI's June 7, 2002, response to the Form FDA-483 for the May 29 to June 3, 2002, inspection to which URI had attached copies of the same falsified and discrepant records that URI previously provided to the FDA investigator during the inspection. FDA's review of the response disclosed continuing inconsistencies with the results of the inspection and investigation.

Based on FDA's inspectional and investigational results, FDA has determined that URI willfully engaged in violative recordkeeping practices and provided false manufacturing records to FDA as corrective actions for the previously noted deficiencies. Additionally, URI's June 7, 2002, response to the Form FDA-483 demonstrates that URI willfully continued to submit falsified documents to FDA.

FDA also notes that URI has had a history of noncompliance with the applicable standards and regulations as shown by significant deviations that were documented during previous inspections of URI. Among those various deviations were discrepancies in URI's test result records, including discrepancies in the test results for the antibody to HIV type 1. FDA emphasized the seriousness of URI's various deviations in letters to URI, including a notice of adverse findings letter dated October 20, 1988, a notice of adverse findings letter dated September 26, 1989, a warning letter dated October 19, 1992, and a warning letter dated July 20, 2000.

**URI Objections to FDA Finding No. 3:**

URI objects to FDA Finding No. 3 to the extent FDA contends that URI intentionally falsified documents and knowingly submitted false documents to the FDA.

**Exhibit 3-A** is a copy of a "Testing Status Report" found in URI's files which clearly indicates that unit 0729718 initially had a test result of "R" or reactive for HIV. **Exhibit 3-A** was in URI's files during the FDA inspection and the FDA investigators saw this document. **Exhibit 3-B** is a "Transfer Report" from CIRBC dated May 12, 2001

indicating that on that date CIRBC automatically conducted a re-test of the HIV test for unit for 0729718 and obtained a result of "N" or non-responsive. This document was also in URI's files during the FDA inspection. It is standard procedure for CIRBC to automatically re-test a unit if and when it obtains a positive test result. This is because it is possible to obtain false positives. As these documents show, when CIRBC first tested unit 0729718 on May 5, 2001, it obtained a positive test result and then, within a week, CIRBC re-tested it and obtained a negative result.

**Exhibit 3-C** is a copy of a false test result purportedly submitted by CIRBC for unit 0729718 showing a result of "N" for the HIV test. **Exhibit 3-C** is one of the documents that allegedly obtained from CIRBC on Saturday, June 1, 2002, and her initials are found at the bottom of the page where she dated the document 6-3-02.

URI submits that there was no reason for URI to falsify these documents because, as indicated above, CIRBC re-tested the sample in question and found it to be non-reactive for HIV. URI has since learned that , evidentially realizing that she had made a mistake, tried to cover up the problem by creating new documents. However, upon closer examination of these false documents, it becomes clear that could not have been operating alone. The font used in the facts legends found on these false documents could not have been made at URI. Instead, it appears clear that someone at had to assist in creating these false documents.

First, the series number on **Exhibit 3-C** is "7899" but the original series number was "1995." It appears that (and perhaps others) found a one-item test report form and altered it to purportedly show results for unit 0729718. Second, the fax date on **Exhibit 3-C** is May 9, 200, which is nearly one year prior to URI's initial request for tests on unit 0729718. Third, URI has determined that it did not receive any faxes from CIRBC on May 9, 2000. And fourth, URI has reviewed it files and determined that the fax legend used by CIRBC changed in June 2000; thus, the legend on **Exhibit 3-C** is inconsistent with the legend used by CIRBC at the time **Exhibit 3-C** was allegedly faxed to URI.

All this leads URI to the conclusion that alteration on **Exhibit 3-C**, and the other falsified documents, could not have been done at URI. URI has investigated the type face of the printers and computers at URI and none of them match up with the type used on the altered documents.

**URI Request for a Hearing on Objections to FDA Finding No. 3:**

Pursuant to 21 CFR § 12.22, URI requests a hearing on each of the matters objected to above. At a hearing, URI will present the evidence and testimony discussed above to establish that URI did not willfully falsify documents and/or submit false documents to the FDA.

**URI Compliance History**

In its Form-483, the FDA stated that URI had a history of non-compliance. URI admits that it has had problems in the past as outlined in the Form-483. However, none of past problem involved "willful" falsification and intentional submission of false documentation to the FDA. In addition, to the best of URI's knowledge, those past problems were never repeated.

Finally, if these objections and requests for a hearing are deficient or fail to meet the regulatory requirements in some way, URI requests the opportunity to amend and/or supplement these objections and requests accordingly.

Very truly yours,

David J. Hensel

DJH:df

97850v1

**CENTRAL INDIANA REGIONAL BLOOD CENTER, INC.**
**Indianapolis, Indiana 46208**

# DONOR TESTING AGREEMENT

**Provided by:**

Central Indiana Regional Blood Center, Inc.
3450 North Meridian Street
Indianapolis, Indiana 46208

**Provided to:**

Universal Reagents, Inc.
2858 N. Pennsylvania
Indianapolis, Indiana 46205

This agreement is entered into this first day of July, 2001 by and between Central Indiana Regional Blood Center, Inc. (hereinafter "CIRBC") and Universal Reagents, Inc. (hereinafter "URI").

**WITNESSETH:**

**WHEREAS, URI** is a blood donor center with facilities located in Indianapolis, Indiana; and

**WHEREAS, CIRBC** is duly licensed by the State of Indiana as a Blood Center and is a Health Care Provider under Indiana's Medical Malpractice Act of 1975, as amended, licensed by the State of Indiana, accredited by the American Association of Blood Banks (AABB), licensed by the Food and Drug Administration (FDA) and provides blood, blood components, donor testing and reference laboratory services; and

**WHEREAS, URI** desires to have **CIRBC** provide specified testing services during the term of this Agreement;

**NOW, THEREFORE,** in consideration of the mutual covenants and agreements contained in this agreement, the parties agree as follows:

## I. SERVICES

CIRBC will provide infectious disease and other testing on donor blood collected by URI and will report those results.

## II. OPERATIONAL REQUIREMENTS

### A. Required Tests and Methodology

Testing will be performed in accordance with CIRBC's current SOPs (standard operating procedures), manufacturer's specifications and written recommendations, AABB (American Association of Blood Banks) guidelines, and FDA (Food and Drug Administration)/ISDH (Indiana State Department of Health)/ CLIA (Clinical Laboratory Improvement Amendments) regulations.

# UNIVERSAL REAGENT, INC.

## OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT A**

Serological Test for Syphilis:
Indiana State Department of Health Laboratory
by Fluorescence Treponema Antibody test

Confirmatory testing for HIV and HCV will be performed by the FDA-licensed tests noted above. Neutralization will be performed on HBsAg EIA positive samples. FTA testing will be performed on positive TP samples.

**3. Individual Tests**

Individual tests, rather than the URI profile, will be performed on donor/patient samples when specifically requested by URI at the time of sample packaging for shipment. CIRBC will provide requisitions to facilitate this process.

**4. Sample Positive Identification**

CIRBC will use a method of sample positive identification (eg. barcodes) for all testing conducted, except manual testing.

**5. Discrepancy Resolution.**

All discrepancies identified by URI will be investigated and resolved by CIRBC in the most expeditious manner possible; all relevant supporting documentation will be provided by CIRBC to URI.

**6. Testing Errors or Omissions**

CIRBC will immediately notify URI by telephone upon discovery of any testing errors or omissions related to URI's samples; written confirmation of such errors will follow. FDA reportable errors will be formally communicated within 72 hours of discovery.

**7. Changes in Test Procedures**

Changes in test procedures, which include modifications to or improvements in the sensitivity/specificity of a test, methodology or instrumentation described in 1 or 2 above or the addition of a new required test, will be formally communicated in writing, after preliminary consultation with URI. The prices referred to herein are based on the use of Abbott technology.

**8. Back Testing**

Back testing of current inventory, if required, will be completed as expeditiously as possible. If CIRBC has not been required to retain samples, URI will provide stored samples for the testing.

**IN WITNESS WHEREOF, CIRBC** and **URI** have duly executed this Agreement on the date first written above.

"CIRBC"
CENTRAL INDIANA REGIONAL BLOOD CENTER, INC.

BY _____
President and CEO

"URI"
UNIVERSAL REAGENTS, INC.

BY _____
Executive Vice President

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT B**

On Thursday, May 30th, 2002 or Friday, May 31st, 2002 I made several telephone calls to Indiana Blood Center in regards to Viral test results on more than one sample of donor draws. On the first call I spoke to a female employee and asked her to fax results for lot numbers on incomplete tests, which I gave to her. I do not remember those lot numbers. Heather may have those numbers. The second time I spoke to Tara. I told her that I needed the results on those same lot numbers. I went to IBC on that same Thursday or Friday at midday. I signed in at the front information desk. I spoke to Pat the receptionist for a few minutes. I spoke to a friend of mine Terry that I knew at IBC. I then talked to Tara when she came down on the elevator because I needed some results. She gave me test results on what I thought were two different lots. I recall noticing that the test result sheets were different from the normal test result sheets, which we receive at Universal Reagents, Inc. from IBC. The result sheets were a different format. There were more numbers than what I requested and those numbers I did not recognize as being from URI. Upon my return to URI, I noted that Leigh Anne from the FDA was leaving for lunch. I gave Heather the results I had received from IBC.

On Saturday, June 1st, 2002 I came to URI in the late afternoon. I checked to see if any further results had been faxed to us. There were test results on the fax machine from IBC. I looked at them and placed them back on the fax machine. I went to see if there were test results on my desk mixed in with other paper work. There was none. I then went over to IBC Distribution that same afternoon and spoke to a male employee and told him that I needed these test results desperately. I gave him our fax number. He said that he would see what he could do about getting us the test results. I spoke to someone else that I knew that worked at IBC for about 10 minutes before leaving. I do not recall her name but she works as I believe in recruiting. I left at that time to return to URI. I waited there shortly and when I did not receive the fax I went back up to IBC Distribution. I went in and a female worker told me that the test results were on the desk to my left. I told her thanks, picked up the results, and left. I returned to URI a 3rd time where I placed the test results on Ken's chair. I left and went to McDonalds and to

's home. That was at approximately 9:00 p.m.

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT C**

To: Don Foster

From: Heather Nieman Heather Nieman

Date: July 18, 2002

CC: Viral Markers

In regards to the suspected doctored viral marker results:

On Friday, May 31, 2002, it was brought to my attention that morning by Leigh Ann Meyers, FDA investigator, that it appeared we had viral marker results missing. The news was passes on to Ken Springer and to examine the data, contact IBC, and explain the situation. When Leigh Ann Meyers left at noon, URI did not have an answer. The answer, as well as others, was expected on Monday, June 3, 2002.

I came into the office on Sunday, June 2, 2002 to compile data and type up a formal response. Upon arrival, I did not expect to have a legitimate answer to the question, as I was the last one in the office on Friday. While working on this project, I went into Ken Springer's office to get some other information. I found a pile of viral marker results on Mr. Springer's chair that appeared to be left there for him. The papers were the missing viral marker results. I did wonder where they came from but assumed that they did come in Friday afternoon without my knowledge. I used these results as provided them to Leigh Ann Meyers on Monday, June 3, 2002.

On Monday, June 3, 2002, Ms. Meyers received the data and did question the quality of the results and asked me to acquire a clean copy for her and forward it with our response. That afternoon I contacted both Tara in the lab and Marianne in the business office both to say Thank You and to receive a clean copy of the results. Neither one had faxed the results and had no idea who had. I made the assumption that it was another individual that either or Mr. Springer contacted on Friday. A couple days later a clean copy of the results were in my 'IN' basket.

I am confident that, if there was doctoring of this paperwork, it was not done in our office. We do not have the capabilities.

In response to the investigation into the allegedly doctored viral marker results discovered at Universal Reagents during the FDA audit on May 29, 2002 through June 3, 2002, Universal Reagents looked into the situation very closely. It is agreed upon that the documents do appear to be altered from their original format; however, we are confident that an employee of Universal Reagents did not do any alterations. Included with these findings are statements from and Heather Nieman. These statements detail how the results were obtained by Universal Reagents and provided to the FDA.

Universal Reagents inspection into this situation noticed a few significant pieces of information. First is that the alterations were not done on the computer. The alterations were crudely done by old fashion cutting and pasting and/or handwriting. The most important is the results for unit 0729718. It appears the method of alteration for this unit was to paste the unit number onto the test results for another unit due to the fact that the unit number is crooked and truncated. The sequence number for this particular test is 7899 and in looking through all viral marker results we found unit 0728314 to be included in sequence 7899 and was tested on 7/22/00. The fax banner on the copy Universal Reagents has of those test results indicate the results were faxed on 7/24/00 and the page of the transmittal that has this format is page 2.

Unit 0729718 was drawn on 4/30/01. The banner on the altered report reads that it was faxed on 5/9/00 and is page 1. There are two things wrong with this particular sheet:

1. The date is a year earlier than it should be.
2. The banner was changed by Indiana Blood Center in the middle of June 2000, indicating a new fax machine. Prior to that date the banner was a different font and had both CIRBC and Universal Reagents spelled out.

It is the third point that leads allows us to believe that Universal Reagents could not have doctored the form. In order to create a banner prior to the date of the new fax machine, the date must have been changed on the machine and a fax created. Universal Reagents does not have access to Indiana Blood Center's fax machine and therefore could not have created a banner for 5/9/02.

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT D**

**Universal Reagents, Inc**
2858 Pennsylvania St
Indianapolis, IN 46205
(317) 926-0006 phone
(317) 926-0014 fax
www.universalreagents.com

# 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.

In response to the investigation into the allegedly doctored viral marker results discovered at Universal Reagents during the FDA audit on May 29, 2002 through June 3, 2002, Universal Reagents looked into the situation very closely. There are three documents in question. Copies of the documents are attached as exhibit A-C. The documents do appear to be altered from their original format; however, we are confident that an employee of Universal Reagents did not do any alterations. Included with these findings are statements from and Heather Nieman. These statements detail how the results were obtained by Universal Reagents and provided to the FDA.

Universal Reagents inspection into this situation noticed a few significant pieces of information. First is that the alterations were not done on the computer. The alterations were crudely done by old fashion cutting and pasting and/or handwriting. The most important is the results for unit 0729718. It appears the method of alteration for this unit was to paste the unit number onto the test results for another unit due to the fact that the unit number is crooked and truncated. The sequence number for this particular test is 7899 and in looking through all viral marker results we found unit 0728314 to be included in sequence 7899 and was tested on 7/22/00. The fax banner on the copy Universal Reagents has of those test results indicate the results were faxed on 7/24/00 and the page of the transmittal that has this format is page 2.

Unit 0729718 was drawn on 4/30/01. The banner on the altered report reads that it was faxed on 5/9/00 and is page 1. There are two things wrong with this particular sheet:

1. The date is a year earlier than it should be.
2. The banner was changed by Indiana Blood Center in the middle of June 2000, indicating a new fax machine. Prior to that date the banner was a different font and had both CIRBC and Universal Reagents spelled out.

It is the third point that leads allows us to believe that Universal Reagents could not have doctored the form. In order to create a banner prior to the date of the new fax machine, the date must have been changed on the machine and a fax created. Universal Reagents does not have access to Indiana Blood Center's fax machine and therefore could not have created a banner for 5/9/02.

Another thing was discovered during this inspection regarding the hand written results on the report. This is not the first time such an occurrence has happened. Attached is a report from 1/12/02, in which the HIV result for unit 0730820 was handwritten.

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

---

**August 11, 2003**

**EXHIBIT E**

**UNIVERSAL REAGENTS, INC.**
2858 North Pennsylvania Street
Indianapolis, Indiana 46205
PHONE: (317) 926-0006
TOLL FREE: (800) 588-8546
FAX: (317) 926-0014

On July 17, 2002 FDA agent Leigh Anne Myers and special agent Kag Cagnoni came to Universal Reagents. They were looking for answers concerning Viral Marker results that did not appear to be authentic. The FDA Audit occurred on May 29, 30, & 31 and concluded on June 3, 2002. In the initial analysis for the viral markers in question, during the audit, test results for lots 0729859, 0729718, 0730860, 0730900, 0730911, and 0730912 were found to be incomplete. This prompted item number 1 on FDA Form 483 from the audit. Please see attached. The completed results, which were originally misplaced in the Viral Marker Book, were eventually found and placed in proper order in the URI Viral Marker Book. Copies of those test results were sent in the 483 response to the FDA. Ms. Myers stated that upon further investigation of the viral documents she believed that they had been tampered with or forged. Mr. Cagnoni was with her as a special investigator. Ms. Myers said that she then had gone to Indiana Blood Center to check on the verification of the documents. At that time IBC employees said that they had not sent these particular test results to URI.

When Myers and Cagnoni came to URI they met with Ken Springer. Mr. Cagnoni asked if they could speak to Heather Nieman. Heather Nieman was unavailable at that time. He then asked to speak to Don Foster and . was questioned about this incident and she said she had no idea how the documents were changed. During the review of the documents by URI employees it was noted that the test results were either printed by hand or pieced together and then photo copied. URI began an investigation into this matter to try to explain the inaccuracies and the attached responses from Heather Nieman and are explanations from that investigation. URI feels that has had a hand in the perpetration of these documents. A meeting of both parties will be arranged in order to review all the information concerning this matter.

Disposition on this matter is not finalized as of present.

Ken Springer
July 30, 2002

Ken Springer

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT F**

UNIVERSAL REAGENTS, INC.

## QUALITY ASSURANCE SHIPMENTS

**PURPOSE:** To insure the safety and the quality of the product. To provide a written approved procedure that outlines and instructs on specific checks that must be verified as acceptable before plasma units are released for in house use or for sale.
**GENERAL:** Quality Assurance must insure that all safety requirements are met for shipment according to **STATE** and **FEDERAL REGULATIONS.**

**PROCEDURE:** Perform review of all test results before plasma is released. Units are held in Quarantine until all required laboratory tests are completed. Quality Assurance must insure that all test results are documented correctly, all reviews are complete, and all results are acceptable. When testing is finalized, Product Histories (LAB-100 REV.01-06-98) are completed with all test data and given to the Product Manager. The Product Manager then gives all completed Product History data to Quality Assurance for QA.

1. Review SPE results where applicable
2. Review Drug screens where applicable
3. Review ALT results where applicable
4. Review HIV-1
5. Review HIV-2
6. Review HIV-1 Ag
7. Review HBsAg results
8. Review HCV results
9. Check label for accuracy
10. Donor number
11. Lot number
12. Expiration Date
13. Name of Product or Antibody present in unit
14. Total Volume
15. Proper storage Temperature

**Insure that NDDR check has been performed, Case Verification Log must be completed, and Quality Assurance Review of Test Results for Shipment Release must be completed. All forms must be attached to shipment package and placed in Quality Assurance File. (SOP 200.03 & 200.05)**

Copies of SOP 200.03 and Actual Viral Marker Test Sheet Results will be sent to customer as confirmation for completed tests.

**SOP 200.02**
**REVISED 11-07-02**

**APPROVED** Ken Springer 11/7/02
Quality Assurance MGR

UNIVERSAL REAGENTS, INC.

# QA REVIEW OF TEST RESULTS FOR SHIPMENT RELEASE

CASE#_____

DONOR#_____

DATE OF SHIPMENT_____

LOT#_____

PLASMA TYPE_____

BLEED DATE_____

EXPIRATION DATE_____

VOLUME_____

| TEST RESULTS FOR: | NEGATIVE | POSITIVE |
|---|---|---|
| HIV 1 | _____ | _____ |
| HIV 2 | _____ | _____ |
| HIV-AG | _____ | _____ |
| HBsAg | _____ | _____ |
| HCV | _____ | _____ |
| SYPH | _____ | _____ |
| ALT | _____ | _____ |
| DRUG | _____ | _____ |

MANAGEMENT REVIEW_____DATE_____

QA REVIEW_____DATE_____

SOP 200.03

REVISED 11/07/2002

APPROVED Ken Springer 11/7/02
Quality Assurance MGT

UNIVERSAL REAGENTS, INC.

# QA SHIPMENT RELEASE

DATE OF REVIEW_____ PRODUCT REVIEWED_____

CASE#_____ POOL LOT#_____

| LOT # REVIEWED | Exp. Date | LOT # REVIEWED | Exp. Date | LOT # REVIEWED | Exp. Date |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

REASON FOR REVIEW:_____

MANAGEMENT REVIEW_____DATE_____

QA REVIEW_____DATE_____

SOP 200.05
3/9/01

APPROVED S. Diane Hering 3.9.01
Training Manager

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 1-A**

# TRANSFER REPORT

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46208-9990

PAGE: 1 OF 1
DATE: 2/11/02
TIME: 17:20
TECH: MRH

| SAMPLE ID | SPCN | HBS | HTV | HBC | ALT | ARV | RUB | CMV | SXD | ABO | CONC | HT1 | CHI | HCV | HAG |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0730893 | 6315 | N | N | | N | | | | | | 6 | N | | N | N |
| 0730894 | 6315 | N | N | | N | | | | | | 25 | | | N | N |
| 0730895 | 6315 | N | N | | N | | | | | | 5 | | | N | N |
| 0730896 | 6315 | N | N | | N | | | | | | 54 | | | N | N |
| 0730897 | 6315 | N | N | | N | | | | | | 9 | | | N | N |
| 0730898 | 6315 | N | N | | N | | | | | | 9 | | | N | N |
| 0730900 | 6315 | | | | N | | | | | | 4 | | | N | N |
| 0730901 | 6315 | N | N | | N | | | | | | 10 | | | N | N |
| 0730902 | 6315 | N | N | | N | | | | | | 9 | | | N | N |
| 0730903 | 6315 | N | N | | N | | | | | | 8 | | | N | N |
| 0730905 | 6315 | N | N | | N | | | | | | 12 | | | N | N |
| 0730906 | 6315 | N | N | | N | | | | | | 31 | | | N | N |
| 0730907 | 6315 | N | N | | N | | | | | | 6 | | | N | N |
| 0730908 | 6315 | N | N | | N | | | | | | 6 | | | N | N |
| 0730909 | 6315 | N | N | | N | | | | | | 16 | | | N | N |
| 0730910 | 6315 | N | N | | N | | | | | | 11 | | | N | N |
| 0730911 | 6315 | | | | N | | | | | | 9 | | | N | N |
| 0730912 | 6315 | | | | N | | | | | | 10 | | | N | N |

REVIEWED BY _____ DATE 2/11-02

# UNIVERSAL REAGENT, INC.

## OBJECTION AND REQUEST FOR HEARING

---

**August 11, 2003**

**EXHIBIT 1-B**

Central Indiana Regional Blood Center
3450 N. Meridian St.
Indianapolis, IN 46208

17:23 / 02/11/02
File Time/Date

TRANSMITTING LAB DATA TRANSFER SYSTEM

TRANSFER PC MAINFRAME UNIT REJECTION REPORT
Version 2.1

| UNIT NUMBER | HBS | HIV | HBC | ALT | ABS | RPR | CMV | BLD TYP | ALT CON | HTL | CHO CON | HCV | HAG |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0730893 | N | N | N | | | | | | 6 | N | | N | N |
| 0730894 | N | N | N | | | | | | 25 | | | N | N |
| 0730895 | N | N | N | | | | | | 5 | | | N | N |
| 0730896 | N | N | N | | | | | | 54 | | | N | N |
| 0730897 | N | N | N | | | | | | 9 | | | N | N |
| 0730898 | N | N | N | | | | | | 9 | | | N | N |
| 0730900 | | | N | | | | | | 4 | | | N | N |
| 0730901 | N | N | N | | | | | | 10 | | | N | N |
| 0730902 | N | N | N | | | | | | 9 | | | N | N |
| 0730903 | N | N | N | | | | | | 8 | | | N | N |
| 0730905 | N | N | N | | | | | | 12 | | | N | N |
| 0730906 | N | N | N | | | | | | 31 | | | N | N |
| 0730907 | N | N | N | | | | | | 6 | | | N | N |
| 0730908 | N | N | N | | | | | | 6 | | | N | N |
| 0730909 | N | N | N | | | | | | 16 | | | N | N |
| 0730910 | N | N | N | | | | | | 11 | | | N | N |
| 0730911 | | | N | | | | | | 9 | | | N | N |
| 0730912 | | | N | | | | | | 10 | | | N | N |

*** End Report ***

2-11-02

# UNIVERSAL REAGENT, INC.

## OBJECTION AND REQUEST FOR HEARING

---

**August 11, 2003**

**EXHIBIT 1-C**

# TESTING STATUS REPORT

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46208-9990

SEQUENCE: 6315
PAGE: 1
DATE: 2/11/02
TIME: 17:17

| STU SAMPLE ID | TEST CT | TESTING STATUS | | | | | | | | | | | | | | COMMENTS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ABORH | ABO | HIV | HBC | LPN | ALT | HBV | RPR | SYC | HCV | CHG | HBC | PTZ | | |
| 1-0730P93 | | | N | N | | | N | | | | N | N | | N | | 02/08/02 |
| 2-0730894 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 3-0730895 | | | I | N | | | N | | | | | N | | N | | 02/08/02 |
| 4-0730896 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 5-0730897 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 6-0730898 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 7-0730899 | | | | | | | N | | | | | N | | N | | 02/08/02 |
| 8-0730901 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 9-0730902 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 10-0730904 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 11-0730905 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 12-0730906 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 14-0730907 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 16-0730908 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 15-0730909 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 16-0730910 | | | N | N | | | N | | | | | N | | N | | 02/08/02 |
| 17-0730911 | | | | | | | N | | | | | N | | N | | 02/08/02 |
| 18-0730912 | | | | | | | N | | | | | N | | N | | 02/08/02 |

REVIEWED BY: ____ DATE: 2/11/02

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 1-D**

Central Indiana Regional Blood Center
3450 N. Meridian St.
Indianapolis, IN 46208
TRANSMITTING LAB DATA TRANSFER SYSTEM

File Time/Date

TRANSFER PC MAINFRAME UNIT REJECTION REPORT
Version 2.1

| UNIT NUMBER | HBS | HIV | HBC | ALT | ABS | RPR | CMV | BLD TYP | ALT CON | HTL | CHO CON | HCV | HAG |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0730893 | N | N | | N | | | | | 6 | N | | N | N |
| 0730894 | N | N | | N | | | | | 25 | | | N | N |
| 0730895 | N | N | | N | | | | | 5 | | | N | N |
| 0730896 | N | N | | N | | | | | 54 | | | N | N |
| 0730897 | N | N | | N | | | | | 9 | | | N | N |
| 0730898 | N | N | | N | | | | | 9 | | | N | N |
| 0730900 | N | N | | N | | | | | 4 | | | N | N |
| 0730901 | N | N | | N | | | | | 10 | | | N | N |
| 0730902 | N | N | | N | | | | | 9 | | | N | N |
| 0730903 | N | N | | N | | | | | 8 | | | N | N |
| 0730905 | N | N | | N | | | | | 12 | | | N | N |
| 0730906 | N | N | | N | | | | | 31 | | | N | N |
| 0730907 | N | N | | N | | | | | 6 | | | N | N |
| 0730908 | N | N | | N | | | | | 6 | | | N | N |
| 0730909 | N | N | | N | | | | | 16 | | | N | N |
| 0730910 | N | N | | N | | | | | 11 | | | N | N |
| 0730911 | N | N | | N | | | | | 9 | | | N | N |
| 0730912 | N | N | | N | | | | | 10 | | | N | N |

*** End Report ***

KRS 6/3/02

6/3/02

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 1-E**

# TEST REQUEST AND REPORT FORM

RELEASED BY: V.K - LCR

Donor Name and Address:
Universal Reagents, Inc.
2338 N. Pennsylvania Street
Indianapolis, IN 46205-4125

Test(s) Requested:
ρ HIV1/2/HBsAg/HCV/HIV-1Ag/ALT
ρ Other HIV 1/2 / HBsAg / HCT / HIV-1 Ag

| | Processed by | Product Type/Code | Blood Date (one blood date per page) | Test Results Received |
|---|---|---|---|---|
| 1 | | | 10/24/02 | |

| Lot Control Number | Date Received | Total Samples | Time | Time | Time VMT | Time ALT |
|---|---|---|---|---|---|---|
| 1070125 CR | 10-25-02 | 6 | Tested By SB | Tested By N/A | Tested By N/A | Tested By N/A |
| Test Facility: ZLB Plasma Services 16500 NW 13th Ave. Miami, FL 33169 | Released By: SZ Date: 10/25/02 Initials: [illegible] Date: 10/25/02 | | Date 10/25/02 - 08 Released By: SZ Date: 10/25/02 | Date Released By: Date: | Date Released By: Date: | Date Released By: Date: |

| Line | Donor Number | Blood Number | Vol | Test Result | Test Result | Test Result | Test Result |
|---|---|---|---|---|---|---|---|
| | 01035 | 0730900 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | 01127 | 0730911 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | 00969 | UR 0730912 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | 01008 | UR 0729859 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | LI 101 | 0715048 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | 00879 | 0730785 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

*VMT Test Results = HIV1/HIV-2, HBsAg, HCV, HIV-1 Ag

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 1-F**

UNIVERSAL REAGENTS, INC.
2858 North Pennsylvania Street
Indianapolis, Indiana 46205
PHONE: (317) 926-0008
TOLL FREE: (800) 588-8546
FAX: (317) 926-0014

October 29, 2002

Marcus A. McMillan
Quality Control Scientist
Diagnostics Division
Gradipore LTD.
22 Rodborough Road
Frenches Forest, NSW 2086
AUSTRALIA

Re: Recall of Plasma Units 0730900 and 0730911

Dear Marcus,

It has been brought to our attention that a shipment made to Gradipore LTD. on April 19, 2002 under your PO#-P14306 contained two Normal Plasma units, which were not completely validated. They are 01035-0730900 (775mL & drawn February 6, 2002) and 01127-0730911 (767mL & drawn February 8, 2002). Both units were sent out to the testing facility, which we were under contract with at the time, for Viral Marker testing on February 8, 2002. All test results were returned by February 11, 2002. As we have recently learned, the HBsAg and HIV ½ tests were missing for both 0730900 and 0730911. The units are normally held in the quarantine freezer until all viral tests are received. Our contract with the testing facility included that they automatically complete all testing or retesting prior to sending out results. They did not do this. In the interim our technician, whom was responsible for filling out all test results on Product History forms, by mistake completed the Product History forms for 0730900 and 0730911 as being non-reactive for all Viral Markers including HBsAg and HIV 1/2. Those units were then pulled from the quarantine freezer and placed in the Normal Plasma minus 40 degree Centigrade freezer for use by our laboratory or for sale purposes. We use the Product History, when they have been completed for all testing, as our guide for picking units to sell to our customers. This has been true for all shipments to Gradipore over the years. This procedure has never failed in the past.

Prior to shipping, all units are checked for correctness of label on the unit bottle, the total volume in the unit, and for Viral Marker tests on the Product History paperwork by a QA representative. Management rechecks the same items and both individuals sign a QA Shipment Release. The product is then ready for use in the lab or for shipment.

URI has made the following changes/corrections concerning this incident.

1) We have changed testing facilities for Viral Marker testing. The units in question have been retested completely by the new facility and found non-reactive for all Viral Markers. A copy of the test record is included with this letter.
2) The technician who made the error is no longer with Universal Reagents, Inc.
3) A recheck of the original Viral Marker test results is now included in the pre-ship QA procedure.

As Gradipore will see from the Viral Marker test data included in this letter these units were and are non-reactive for all viral testing. If you, however, still feel uncomfortable with this incident we would like to offer an opportunity to return these units at our expense under a recall. Please let us know your feelings on this matter as soon as possible. We want you to continue as a valued customer and are willing to work with you. We apologize for any inconvenience this may have caused Gradipore.

Sincerely,

Ken Springer

Kenneth R. Springer
Director of Customer Service

Gradipore

Kenneth R Springer
Universal Reagents, INC.
2585 North Pennsylvania Street
Indianapolis, Indiana 46205

6th November 2002

Dear Ken,

Thank you for your fax and letter dated 29th October 2002 informing Gradipore of the two Normal Plasma units under PO# P14306 which were not completely validated.

I am sure you appreciate the potential issues for both Universal and Gradipore if the donations had been positive for any of the tests.

Universal Reagents has provided Gradipore with good customer service and reliable supply of plasma for some years now and we (Diagnostics, Quality and staff) prefer to resolve current issues rather than change suppliers.

Gradipore need to be confident that Corrective Action undertaken by Universal will effectively minimise the risk of re-occurrence of this type of incident.

Providing us with a copy of your release for sale documents (or a detailed description of the procedure) showing the changes made would be of assistance. This will allow the staff to be satisfied that risk is minimised, and also provide documentary evidence for Gradipore should we need to defend our choice of supplier during the course of any external audit.

I hope that we can quickly close this issue and move on together.

Yours sincerely,

Warwick Dargan
General Manager, Diagnostics.

T:\PUBLIC\Diagnostics\Quality\Customer Complaints\Kenneth R Springer 6th November 2002 WD.doc

Gradipore Ltd ABN 79 001 001 145
22 Rodborough Road, Frenchs Forest NSW 2086 Australia
PO Box 6126 Frenchs Forest NSW 2086 Australia
Telephone 61 2 8977 9000
Facsimile 61 2 8977 9099
Internet www.gradipore.com
Email info@gradipore.com

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

---

**August 11, 2003**

**EXHIBIT 2-A**

# TRANSFER REPORT

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46208-9990

PAGE: 1 OF 1
DATE: 6/ 2/01
TIME: 14:50
TECH: JAB

| SAMPLE ID | SEQ# | HBS | HIV | HBC | ALT | ABY | RPR | CMV | SXD | ABO | CONC | HT1 | CHL | HCV | HAG |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0729847 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729848 | 2365 | N | N | N | | | | | | | 6 | | N | N | |
| 0729849 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729850 | 2365 | N | R | N | | | | | | | 4 | | N | N | |
| 0729851 | 2365 | N | N | N | | | | | | | 7 | | N | N | |
| 0729852 | 2365 | N | N | N | | | | | | | 6 | | N | N | |
| 0729853 | 2365 | N | N | N | | | | | | | 17 | | N | N | |
| 0729854 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729855 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729856 | 2365 | N | N | N | | N | | | | | 5 | | N | N | |
| 0729857 | 2365 | N | N | N | | | | | | | 18 | | N | N | |
| 0729858 | 2365 | N | N | N | | | | | | | 10 | | N | N | |
| 0729859 | 2365 | | | N | | | | | | | 4 | | | | |
| 0729861 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729862 | 2365 | N | N | N | | | | | | | 21 | | N | N | |
| 0729863 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729864 | 2365 | N | N | N | | | | | | | 14 | | N | N | |
| 0729865 | 2365 | N | N | N | | | | | | | 14 | | N | N | |
| 0729866 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729867 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729868 | 2365 | N | N | N | | | | | | | 4 | | N | N | |
| 0729869 | 2365 | N | N | N | | | | | | | 25 | | N | N | |
| 0729870 | 2365 | N | N | N | | | | | | | 6 | | N | N | |
| 0729871 | 2365 | N | N | N | | | | | | | 4 | | N | N | |

REVIEWED BY_____ DATE 6/4/01

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 2-B**

# TESTING STATUS REPORT

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46208-9990

SEQUENCE: 2365
PAGE: 1
DATE: 6/ 2/01
TIME: 15:00

| SEQ SAMPLE ID | TST ST. | TESTING STATUS | | | | | | | | | | | | | | COMMENTS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ABORH | HBS | HIV | HBC | CMV | ALT | ABY | RPR | SXO | HT1 | HCV | CHL | HAG | FTZ | |
| 1-0729847 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 2-0729848 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 3-0729849 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |
| 4-0729850 | | | N | R | | | [N] | | | | | N | | N | | 06/01/01 |
| 5-0729851 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 6-0729852 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 7-0729853 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 8-0729854 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |
| 9 0729855 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |
| 10-0729856 | | | N | N | | | N | | N | | | N | | N | | 06/01/01 |
| 11-0729857 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 12-0729858 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 13-0729859 | | | | | | | N | | | | | | | | | 06/01/01 |
| 14-0729861 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |
| 15-0729862 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 16-0729863 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |
| 17-0729864 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 18-0729865 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 19-0729866 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |
| 20-0729867 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |
| 21-0729868 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |
| 22-0729869 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 23-0729870 | | | N | N | | | N | | | | | N | | N | | 06/01/01 |
| 24-0729871 | | | N | N | | | [N] | | | | | N | | N | | 06/01/01 |

REVIEWED BY_____ DATE 6/4/01

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 2-C**

# TESTING STATUS REPORT

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46206-9990

PAGE: 1
DATE: 6/19/01
TIME: 15:43

RANGES: 0729859 - 0729859

| SEQ SAMPLE ID | TST ST. | TESTING STATUS | | | | | | | | | | | | | COMMENTS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ABORH | HBS | HIV | HBC | CMV | ALT | RBY | RPR | SYB | HTI | HCV | CHL | NAG | |
| 13-0729859 | | | | | N | | N | | | | | N. | | | 06/01/01 |

* Sample not old to complete testing

REVIEWED BY TJT DATE 6/19/01

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

---

**August 11, 2003**

**EXHIBIT 2-D**

# TESTING STATUS REPORT

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46208-9990

PAGE: 1
DATE: 6/19/01
TIME: 15:43

RANGES: 0729859 - 0729859

| REQ SAMPLE ID | TEST ST. | TESTING STATUS | | | | | | | | | | | | | | COMMENTS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ABORH | HBS | HIV | HBC | CMV | ALT | HBY | HPR | SXD | HTL | HCV | CHL | HRG | T2 | |
| 13-0729859 | | | N | N | N | | N | | | | | N | | N | | 06/01/01 |

REVIEWED BY TJH DATE 6/19/01

6/3/02 KAS 6/3/02

# UNIVERSAL REAGENT, INC.

# OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 2-E**

Sent From:
Universal Reagents Inc.
Laboratory Services
Indianapolis, IN 46205
(317) 926-0006

Test Request Form

CIRCL
3450 N. Meridian
Indianapolis, IN 46208
(317) 924-1708

All samples for HIV p24 Ag testing are required to be stored Frozen (-20°C or Colder) from the date of collection until the time of shipment.

Date Sent 5-4-01
Results Received 5-7-01
Tech Initials AP

1 of 2

| Lot # | Donor # | HBsAg S010 | HIV Ag S111 | Anti-HIV 1 S110 | Anti-HCV S105 | ALT S085 | Anti-HTLV I/II S082 | Anti-HBc S040 | RPR | |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 07 29712 | RBC137 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 2 07 29713 | 01014 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 3 07 29714 | 00827 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 4 07 29715 | 01025 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 5 07 29716 | 00825 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 6 07 29717 | 01006 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 7 07 29718 | 01101 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 8 07 29719 | 01094 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 9 07 29720 | 00879 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 10 07 29721 | 00888 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 11 07 29722 | 00909 | ✓ | ✓ | ✓ | ✓ | | | | | |
| 12 07 29724 | 01035 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 13 07 29725 | 01007 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 14 07 29726 | 00876 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 15 07 29727 | 01014 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 16 07 29728 | 01126 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 17 07 29729 | RBC112 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 18 07 29730 | 00969 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 19 07 29731 | 00825 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| 20 07 29732 | 00944 | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |

Form [illegible]

CH [illegible] DCC [illegible] MD [illegible]

# UNIVERSAL REAGENT, INC.

## OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 2-F**

# TEST REQUEST AND REPORT FORM

RELEASED BY: V.K - LCR

Client Name and Address:
Universal Reagents, Inc.
2358 N. Pennsylvania Street
Indianapolis, IN 46205-4125

Test(s) Requested:
ρ HIV1/2/HBsAg/HCV/HIV-1Ag/ALT
ρ Other HIV 1/2 / HBsAg / HCT / HIV-1 Ag

| Processed by | Product Type/Code | Blood Date (one blood date per page) | Test Results Received |
|---|---|---|---|
| 1 | | 10/24/02 | |

| Lab Control Number | Date Received | Total Samples | Test | Test | Test VMT | Test ALT |
|---|---|---|---|---|---|---|
| 1070125 ER | 10-25-02 | 6 | Tested By SB | Tested By N/A | Tested By N/A | Tested By N/A |
| Test Facility: ZLB Plasma Services 16400 NW 13th Ave. Miami, FL 33169 | Released by: SZ Date 10/28/02 | | Date 10-26-02 | Date by Released | Date by Released | Date by Released |

| Logs | Donor Number | Blood Number | Vol | Test Result | Test Result | Test Result | Test Result |
|---|---|---|---|---|---|---|---|
| | 01035 | 0730900 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | 01127 | 0730911 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | 00969 | UR0730912 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | 01008 | UR0729859 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | LI 101 | 0715048 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |
| | 00879 | 0730785 | | NON REACTIVE | NONREACTIVE | NONREACTIVE | |

*VMT Test Results – HIV1/HIV-2, HBsAg, HCV, HIV-1 Ag

# UNIVERSAL REAGENT, INC.

## OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 3-A**

# TESTING STATUS REPORT

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46208-9990

SEQUENCE: 1995
PAGE: 1
DATE: 5/ 5/01
TIME: 16:14

| SEQ SAMPLE ID | TST ST. | TESTING STATUS | | | | | | | | | | | | | | COMMENTS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ABORH | HBS | HIV | HBC | CMV | ALT | ABY | RPR | SXD | HT1 | RCV | CHL | HAG | FTZ | |
| 1-0729712 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 2-0729713 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 3-0729714 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 4-0729716 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 5-0729717 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 6-0729718 | | | N | [illegible] | | | N | | | | | N | | N | | 05/04/01 |
| 7-0729719 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 8-0729720 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 9-0729721 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 10-0729722 | | | N | N | | | | | | | | N | | N | | 05/04/01 |
| 11-0729724 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 12-0729725 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 13-0729726 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 14-0729727 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 15-0729728 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 16-0729729 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 17-0729730 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 18-0729731 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 19-0729732 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 20-0729733 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 21-0729734 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 22-0729735 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 23-0729736 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 24-0729737 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 25-0729738 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 26-0729739 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 27-0729740 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 28-0729741 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 29-0729742 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |
| 30-0729743 | | | N | N | | | N | | | | | N | | N | | 05/04/01 |

REVIEWED BY TJT DATE 5/5/01

# UNIVERSAL REAGENT, INC.

## OBJECTION AND REQUEST FOR HEARING

---

**August 11, 2003**

**EXHIBIT 3-B**

# TRANSFER REPORT

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46208-9990

PAGE: 1 OF 1
DATE: 5/12/01
TIME: 14:35
TECH: JMA

| SAMPLE ID | SEQ# | HBS | HIV | HBC | ALT | ABY | RPR | CMV | SXD | ABO | CONC | HT1 | CHL | HCV | HAG |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0729750 | 2088 | N | N | N | | | | | | | 25 | | N | N | |
| 0729751 | 2088 | N | N | N | | | | | | | 14 | | N | N | |
| 0729752 | 2088 | N | N | N | | | | | | | 10 | | N | N | |
| 0729753 | 2088 | N | N | N | | | | | | | 9 | | N | N | |
| 0729754 | 2088 | N | N | N | | | | | | | 10 | | N | N | |
| 0729755 | 2088 | N | N | N | | | | | | | 12 | | N | N | |
| 0729756 | 2088 | N | N | N | | | | | | | 11 | | N | N | |
| 0729757 | 2088 | N | N | N | | | | | | | 19 | | N | N | |
| 0729758 | 2088 | N | N | N | | | | | | | 11 | | N | N | |
| 0729759 | 2088 | N | N | N | | | | | | | 7 | | N | N | |
| 0729762 | 2088 | N | N | N | | | | | | | 9 | | N | N | |
| 0729763 | 2088 | N | N | N | | | | | | | 20 | | N | N | |
| 0729764 | 2088 | N | N | N | | | | | | | 12 | | N | N | |
| 0729765 | 2088 | N | N | N | | | | | | | 11 | | N | N | |
| 0729766 | 2088 | N | N | N | | | | | | | 14 | | N | N | |
| 0729767 | 2088 | N | N | | | | | | | | | | N | N | |
| 0729768 | 2088 | N | N | N | | | | | | | 9 | | N | N | |
| 0729769 | 2088 | N | N | N | | | | | | | 10 | | N | N | |
| 0729770 | 2088 | N | N | N | | | | | | | 17 | | N | N | |
| 0729771 | 2088 | N | N | N | | | | | | | 9 | | N | N | |
| 0729772 | 2088 | N | N | | | | | | | | | | N | N | |
| 0729773 | 2088 | N | N | | | | | | | | | | N | N | |
| 0729774 | 2088 | N | N | N | | | | | | | 8 | | N | N | |
| 0729775 | 2088 | N | N | N | | | | | | | 11 | | N | N | |
| 0729776 | 2088 | N | N | N | | | | | | | 9 | | N | N | |
| 0729777 | 2088 | N | N | | | | | | | | | | N | N | |
| 0729778 | 2088 | N | N | N | | | | | | | 6 | | N | N | |
| 0729779 | 2088 | N | N | N | | | | | | | 7 | | N | N | |
| 0729780 | 2088 | N | N | N | | | | | | | 68 | | N | N | |
| 0729781 | 2088 | N | N | N | | | | | | | 22 | | N | N | |
| 0729782 | 2088 | N | N | N | | | | | | | 9 | | N | N | |
| 0729718 | 1995 | N | N | N | | | | | | | 6 | | N | N | |

5-14-01

REVIEWED BY _____ DATE 5-12-01

# UNIVERSAL REAGENT, INC.

## OBJECTION AND REQUEST FOR HEARING

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**August 11, 2003**

**EXHIBIT 3-C**

[redacted]

DATA MANAGEMENT SYSTEM
CENTRAL INDIANA REGIONAL BLOOD CENTER
3450 N. MERIDIAN STREET
INDIANAPOLIS, IN 46208-9990

SEQUENCE: 7899
PAGE:
DATE:
TIME:

| EQ SAMPLE ID | TST ST. | TESTING STATUS | | | | | | | | | | | | | | COMMENTS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ABORH | HBS | HIV | HBC | CMV | ALT | ABY | RPR | SXD | HTI | HCV | CHL | HAG | ST2 | |
| 1729718 | | | N | N | | | N | | | | | N | | N | | |

REVIEWED BY _____ DATE _____

1/05 cl 3/17 6302