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Subject: ***Laboratory Information System - Post Implementation Review***
Audit Project 2011-14

The final audit report for Laboratory Information System – Post Implementation Review, Audit Report 2011-14, is attached. We would like to thank all personnel who participated in the audit for their cooperation and assistance.

Because we were able to reach agreement regarding corrective actions to be taken in response to the audit recommendations, a formal response to the report is not requested.

The findings included in this report will be added to our follow-up system. While management corrective actions have been included in the audit report, we may determine that additional audit procedures to validate the actions agreed to or implemented are warranted. We will contact you to schedule a review of the corrective actions, and will advise you when the findings are closed.

UC wide policy requires that all draft audit reports, both printed and electronic, be destroyed after the final report is issued. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel, or destroy them. AMAS also requests that draft reports not be photocopied or otherwise redistributed.

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Attachment

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AUDIT & MANAGEMENT ADVISORY SERVICES

UC San Diego Health System Clinical Laboratories
Laboratory Information System
Post Implementation Review
June 2012

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Project Number: 2011-14

Table of Contents

I. Background

Audit & Management Advisory Services (AMAS) has completed a post implementation review of the UCSD Health System (UCSDHS) Clinical Laboratories Information System with a focus on test order, charge capture, and billing interface processes as part of the approved audit plan for FY 2010-11. This report summarizes the results of our review.

The UCSDHS is comprised of UCSD Medical Centers Hillcrest and La Jolla, the UCSD Moore's Cancer Center, the Shiley Eye Center, and primary care and specialty clinics. Laboratory services are provided to UCSDHS operations by the UCSD Clinical Laboratories (Laboratories), a network of specialty laboratories. The Laboratories are organized for financial management purposes as eleven separate financial cost centers.

During November 2011, a number of Laboratories relocated from the Hillcrest Medical Center to the Center for Advanced Laboratory Medicine (CALM) in La Jolla. The schedule below provides a snapshot of Laboratory cost centers and locations before and after the relocation occurred.

Pre November 2011	Post November 2011
Blood Bank Lab - Hillcrest	Blood Bank Lab - Hillcrest
Blood Bank Lab - Thornton	Blood Bank Lab - Thornton
Cancer Center Lab	Cancer Center Lab
Clinical Lab - Hillcrest	Clinical Lab - Hillcrest
Clinical Lab - Thornton	Clinical Lab - Thornton
	Clinical Lab - CALM
Immunogenetics & Transplant Lab - Torrey Pines	Immunogenetics & Transplant Lab - CALM
Medical Genetics Lab - UCSD Campus	Medical Genetics Lab - CALM
Microbiology - Hillcrest	Microbiology - CALM
Pathology - Hillcrest	Pathology - Hillcrest
Phlebotomy - Hillcrest	Phlebotomy - Hillcrest
Point of Care	Point of Care

Laboratory Information System (LIS) Implementation

The Laboratories are in the process of implementing Soft Computer Company's (SCC) Laboratory Information System (LIS) suite SoftLab II (SoftLab) to replace the ASPYRA system. SoftLab provides support for robotic testing equipment and is internet enabled. It also supports direct customer invoicing.

The SoftLab implementation will be completed in three phases. Phase I included the SoftLab and SoftMic modules, which support general Laboratory and Microbiology operations. The system go-live date for Laboratories included in Phase I was November 9, 2010. Phase II of the implementation is scheduled for July 2012, and will include the SoftGene module. Phase III of the project will focus on implementing the SoftBank II module in the Blood Bank Labs. The projected go-live date for Phase III has not been determined.

The schedule below provides an overview of the SoftLab implementation Phase for each Laboratory.

Laboratory	Soft Phase
Blood Bank Lab - Hillcrest	III
Blood Bank Lab - Thornton	III
Cancer Center Lab	I
Clinical Lab - CALM	I
Clinical Lab - Hillcrest	I
Clinical Lab - Thornton	I
Immunogenetics & Transplant Lab - CALM	II
Medical Genetics Lab - CALM	II
Microbiology - CALM	I
Phlebotomy - Hillcrest	I
Point of Care	I

LIS Integration with UCSDHS Systems

After specimens are accessioned into SoftLab, tests are processed within the SoftLab Clinical Module. Charges for completed tests are managed in the SoftLab Accounts Receivable (AR) Module, where they are reviewed and validated prior to being accumulated in the daily charge file.

Bi-directional interfaces have been implemented between SoftLab and Epic, the UCSDHS electronic health record (EHR) application. Epic transmits electronic test orders to SoftLab for processing. When test results have been completed, they are transmitted from SoftLab to Epic. The medical record number assigned to each UCSDHS patient is captured on all documents generated during health care visits to ensure that related information is included in the patient's EHR.

SoftLab also generates test charges. At the end of each business day, SoftLab compiles and transmits a charge file to the hospital Financial Management System (FMS) billing system. SoftLab transmits a patient number with each charge to direct charges to the correct patient account[1]. Laboratory staff are at times required to select the appropriate patient account number when accessioning specimens into the system.

Test Order Pathways

Laboratory orders, which are also referred to as requisitions, are electronically transmitted into SoftLab via the Epic interface, or are keyed into the system when a paper requisition is provided. Emergency Room (ER) test requisitions are sent from the ER

[1] FMS is configured to generate a unique patient account number for each significant episode of care. For example, a unique account may be created for each Emergency Room (ER) visit, inpatient admission, and ongoing clinical service. Therefore, while each patient has a single medical record number, several patient accounts may be active at one time. Patient account numbers are assigned in the Patient Care Information System (PCIS) during the patient registration process.

WebCharts system to a dedicated Laboratory printer, and must be input into SoftLab. This is also the case for orders received via fax from non-UCSD physicians, and various patient care areas that may or may not have implemented Epic. Test results are electronically transmitted to Epic, or faxed/mailed to non-UCSDHS physicians. ***Attachment A*** provides a detailed flowchart of these processes.

Physicians may also enter "standing" test orders into Epic to ensure that an order is available when the patient arrives at the Laboratory for regularly scheduled tests. For example, an order may be created for a patient to have tests performed on the first day of each month, and every two weeks thereafter for the next six months. The initial order is designated in SoftLab as the "parent" and subsequent orders are "children." "Children" orders cannot be altered unless the "parent" order is changed. Epic transmits orders to SoftLab up to 10 days prior to the test due date.

II. Audit Objective, Scope, and Procedures

The objective of our review was to evaluate the effect of the SoftLab implementation planning and execution on the effectiveness of charge generation and transmission processes. The scope of the review included inpatient, outpatient and research related services processed by the Laboratories that implemented SoftLab during Phase I of the project. Therefore, the audit scope included a review of processes and transactions for the period September 2010 through August 2011.

We completed the following audit procedures to achieve the project objective:

- Reviewed Center for Medicare and Medicaid Services (CMS) regulations and references in the Federal Register related to laboratory test billing guidance;
- Evaluated University of California IS-10 requirements, and identified the areas of IS-10 that applied to the SoftLab implementation;
- Interviewed the Laboratory Administrative Director and Compliance Manager to obtain an overview of Laboratory business processes;
- Met with the Laboratory IS team to discuss SoftLab application functionality;
- Reviewed the SCC contract and the system implementation schedule;
- Interviewed the SCC SoftLab implementation support team to discuss the implementation schedule and processes;
- Interviewed the Epic Team[2] to discuss Epic/SoftLab interface issues;
- Met with the Phlebotomy Laboratory Manager to complete an order processing walkthrough;
- Discussed laboratory test billing issues with Patient Financial Services (PFS) Managers;
- Evaluated the DV& Associates, Inc.[3] consulting report for its review of the Laboratory Charge Description Master (CDM)[4]

[2] The Epic Team is comprised of UCSDHS staff assigned to Epic system implementation, maintenance and training.
[3] DV & Associates, Inc. is a coding and reimbursement firm which provides consulting for physicians and facilities in all specialties.

- Reviewed the data in SoftLab Clinical and AR test dictionaries;
- Compared the Laboratory CDM to the SoftLab charge dictionary;
- Outlined specimen accession procedures;
- Analyzed the test volume and associated charges by Laboratory (***Attachment B***);
- Determined the volume of send-out tests for each Laboratory, and assessed the accuracy of send-out tests prices included on the CDM as of (date);
- Evaluated send-out test charges;
- Verified the continuity of information on three samples or 88 manually processed test requisitions from the point of order to the generation and transmission of the charge file to FMS;
- Converted and compared HL-7[5] charge file against SoftLab input analysis; and,
- Analyzed three days of data throughput in the SoftLab application from the point of order to the generation and transmission of the HL-7 charge file to FMS.

Sample Selection and Test Descriptions

Audit tests were performed using SoftLab transaction files and a judgmental sample of paper test requisitions selected from the three day period June 6 through June 8, 2011. These files and documents were used to complete several different types of audit tests described below.

SoftLab transactions were analyzed and compared to HL-7 charge files to evaluate the time lapse between the accession and charge dates. Charges for 23 patients were selected judgmentally for focused review. (***See Report Finding D***)

A sample of 90 paper and electronic test requisitions was selected to verify that test results and charges were consistent with the test included on the order. Ten requisitions from three sources (the ER, Epic and fax) were selected for each of the three days in the sample period for a total of 90 requisitions. Subsequent analysis revealed that only 88 of the 90 requisitions in the original sample met the audit test criteria. (***See Report Findings E and I***)

Send-Out test prices were compared to the CDM to ensure that the charge was based on an accurate cost from the contracted Laboratory. The quantity of tests[6] and CDM charge was secured for all send-out tests. The product of the test quantity and charge was then used to establish a highest to lowest send-out test ranking. Charges for each of the

[4] The hospital Charge Description Master (CDM) is the comprehensive listing of Medical Center procedures, facility and supply charges and their corresponding descriptions, revenue codes and billing codes, including HCPCS II & III, CPT, and modifiers.

[5] Health Level Seven (HL7) is an all-volunteer, non-profit organization involved in development of international healthcare informatics interoperability standards. "HL7" is also used to refer to some of the specific standards created by the organization. HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. v2.x of the standards, which support clinical practice and the management, delivery, and evaluation of health services, are the most commonly used in the world.

[6] Quantity data was obtained from FMS Rev-6 reports.

fourteen send-out tests completed most frequently were then traced to a reference Laboratory price list[7]. (***See Report Finding H***)

III. Conclusion

We concluded that the planning and execution of Phase I of the SoftLab system implementation did not comply with certain IS-10 requirements, resulting in the need for LIS IT and Laboratory management personnel to re-assess charge capture processes after the implementation date. We also noted that system performance continued to improve during audit fieldwork due to the diligence of LIS IT and the Laboratory Compliance Manager to evaluate errors and implement solutions.

AMAS' analysis of orders, and associated charge data for the post implementation period identified additional opportunities for improvement, including some that were unrelated to the SoftLab implementation, yet vital to accurate charge processing. These opportunities were focused on charge data consistency, timeliness, and monitoring; SoftLab data accuracy; and order and charge processing issues. Each of these observations is discussed in more detail in the remainder of this report.

IV. Observations and Management Corrective Actions

A. SoftLab Implementation

The SoftLab application was implemented without full adherence to UC IS-10 requirements. As a result, during the first six months post implementation, SoftLab processes did not fully support Laboratory operational and internal control requirements.

The LIS is a complex, critical application. Thousands of tests are processed and charged each day. Patient care areas rely on laboratory results being available in the EHR on a timely basis, and the charge capture processes must comply with CMS regulations.

UC Policy IS-10: *Systems Development and Maintenance Standards* provides guidance for the key elements of planning, designing and implementing business critical computer applications. IS-10 addresses requirements for systems that are vendor sourced, prototyped or developed by traditional life cycle approach. It calls for the establishment of a Steering Committee comprised of senior-level management to provide strategic direction to the project. Also involved in implementation are other departments that interact with the system, such as Internal Audit, which has only an oversight role.

LIS IT staff collaborated with the SCC implementation support and the Epic Team to design application parameters and interfaces with EHR and the billing

[7] Because ARUP completes approximately 80% of all send-out tests, only tests sent to ARUP were include in this analysis.

systems. However, we were advised that the Epic Inpatient System implementation was dependent upon the implementation of SoftLab, which could not be delayed, and that Revenue Cycle personnel did not participate in implementation activities until User Acceptance Testing[8] was completed before the system go-live date. We were advised by Laboratory management that a written project plan was maintained, but it was not available for review during audit fieldwork.

Phase I laboratories were converted to SoftLab on November 9, 2010. To evaluate the impact of implementation on processed charges, a detailed analysis of the test volume and associated charges for each Phase 1 Laboratory is provided in ***Attachment B***[9]**.** The analysis shows a decrease in test charge volume for several Laboratory cost centers for a short period after implementation. This was likely associated with a three week period in November and December 2010 when charges were held in PFS to ensure that ICD-9 diagnosis coding information was accurately passed to FMS. The actual financial impact could not be determined. However, any loss of billable charges during that time period equates to an additional implementation cost.

We also noted that several improvements to charge capture processes identified in prior internal audit reports (such as the ability of the LIS to append charge modifiers) did not appear to be considered prior to Phase I implementation. Also, a process was not established for periodic synchronization between the LIS charge dictionaries and the CDM.

IS-10 requirements for inclusion of key stakeholders in the implementation process, and the inclusion of all critical pre go-live tasks in a formal work plan would help to ensure that critical functions are considered during system design and test phases.

Management Corrective Actions:

To ensure compliance with IS-10 requirements during future system conversions or significant software updates, Laboratory Management and Information Services should collaborate to ensure that:

1. Key stakeholders are included early in the system implementation process.

2. Full-cycle business process testing is completed before implementation.

[8] User acceptance testing (UAT) – also called beta testing, application testing, and end user testing – is a phase of software development in which the software is tested by the intended users.

[9] FMS Rev-6 report was the data source.

B. SoftLab AR and Laboratory CDM - Data Consistency

The SoftLab AR pending charge list did not include tests transferred from SoftLab Clinical module for which a "no charge" status was appropriate. In addition, certain tests in SoftLab AR were not included in the Laboratory CDM, and the CDM did not include a price for all tests.

The SoftLab Clinical module test list includes all tests that may be ordered. The SoftLab AR test list includes all tests that may result in patient charges. Most often, a one-to-many relationship exists between the tests requisitioned and those resulting in charges. For example one test in the Clinical module may equate to three separate tests in AR, of which only the first and the third are chargeable. There are also instances where a test exists only on the Clinical module list. For example, the Glomerular Filtration Rate (GFR) test is not intended to result in a charge. Therefore, it did not appear on the AR list.

The AR module facilitates charge processing by referencing the CDM. Each test listed in AR has a corresponding CDM service code. Our review of the AR list identified five tests that had no matching CDM entries. Seven additional tests had entries in the AR CDM field, but those entries could not be traced to the CDM. Twenty tests on the CDM had no prices.

Accurate charge generation requires that SoftLab charge codes match and accurately transfer from AR to the CDM. Certain tests on the AR list and the CDM track statistical counts only, and are not meant to result in charges. All fields should be valued to ensure that information is not missing that could result in inaccurate charges or loss of revenue.

Management Corrective Actions:

1. After the completion of audit fieldwork, the Laboratory Compliance Manager identified and corrected a majority of issues noted, and is in the process of analyzing laboratory tests on the CDM for which there is no price but the test are being performed.

2. LIS IT and the Laboratory Compliance Manager will re-evaluate the test code relationships between the Clinical and AR dictionaries and the CDM to ensure completeness and price accuracy.

3. The Laboratory Compliance Manger will implement a periodic quality control review to ensure that the data on the AR test list is complete and accurate, and reconciles to the CDM.

C. SoftLab AR Data Accuracy

The CPT codes in the AR module and the Laboratory CDM were not consistent in some cases.

The AR module has the functionality to process and distribute charges directly to an invoice without utilizing the FMS billing system. Laboratory Administration has discussed using this feature to generate invoices for non-UCSDHS customers in the future. During the SoftLab implementation process, the entire Laboratory CDM was uploaded to the AR module to support the invoice generation process. However, because the CDM is subject to periodic updates as CPT codes are added or deleted by the American Medical Association (AMA), a portion of the original CDM data upload into the AR module became outdated.

AMAS analyzed the data in the AR module dictionaries and identified 43 instances where AR data elements differed from CDM content. Although code differences are not critical until the invoicing process is implemented, a process for completing periodic updates to AR dictionaries with current CDM data had not been documented to help ensure that the data included on invoices to external customers is accurate and complete.

Management Corrective Action:

LIS IT will implement a procedure to update the AR dictionary data with CDM content when CPT codes and laboratory requests for CDM updates are processed by the Revenue Cycle CDM Manager.

D. SoftLab Charges – Timeliness and Monitoring

SoftLab charges were not consistently sent to FMS on a timely basis. In addition, LIS IT did not have all information needed to ensure that completed test orders in the SoftLab Clinical module were passed to SoftLab AR for charge capture.

Medical Center Policy (MCP) 724.1, *Charge Entry* requires that charges be submitted to PFS within 24 hours of the services being provided. Charges received are recognized as revenue when posted, resulting in efficient and timely generation of patient invoices and payer claims.

As previously described, there was not a one-to-one relationship between the tests accessioned into the Clinical module and the charges generated in the AR module. Therefore, to test for charge processing accuracy, a higher level analysis was performed. We obtained the June 6, 2011 Clinical input file and AR HL-7 file and used patient demographic data to determine whether a charge was generated for all accessioned tests on that date.

Our initial analysis showed that 231 patients with accessioned tests did not appear in the AR charge file. Those patients were associated with 896 separate tests comprised of 186 unique test types within the SoftLab system. Of these, 81 test types were associated with a CDM code and should have been included in the charge file each time the test was completed.[10] Further analysis revealed that on the same date of service, 74 of those test types were charged to other patients, but not to those patients with tests missing from the charge file.

To attempt to identify unique characteristics of the patients with missing charges, a random sample of 23 patients was selected and reviewed in detail. Our analysis provided the following information:

- Five patients had test activity in April that was suspended in the Clinical module.
- Four patients had cancelled test orders.
- The charges for nine patients were processed after LIS IT directed the charges to the correct patient numbers.
- The charges for two patients were appropriately directed to bulk accounts, and would not post to their regular accounts.
- The remaining three patients had "no charge" tests or had tests completed at the point of care, which did not generate a direct patient charge.

Although LIS IT performs daily monitoring of the tests transferred to the AR module to identify records that have failed the system "invoice" and "bill" processes,[11] actions required to correct the errors that prevent charges from being transmitted to the billing system are manual and time consuming. In addition, Clinical module data are not visible to LIS personnel, preventing them from reviewing an aged list of pending tests. Therefore, LIS IT may not be aware if tests are not transferred timely from the Clinical module to the AR module to complete charge capture.

Management Corrective Action:

LIS IT will consult with SCC to determine whether an automated exception report could be developed to report tests generated in the Clinical module that have not transferred to the AR module to assist with charge monitoring.

[10] Some tests are not individually listed in the CDM because they are separately tracked for operational purposes only.
[11] Although "invoice" and "bill" are generic business terms, they are actual names of specific tests in SoftLab terminology.

E. Order and Charge Processing Issues

We noted a number of issues in order and charge processing.

To evaluate the accuracy and consistency of Laboratory processes from accession through charge capture, AMAS selected a sample of 88 paper and electronic test requisitions and compared the information submitted on the order to SoftLab test and charge data that was transmitted to FMS. We observed the following issues based on our sample analysis.

1. Unordered Tests Performed

Tests not listed on the requisition were completed for three of 88 (3%) requisitions reviewed.

During audit testing, we noted that tests completed did not appear on the order for three of 88 (3%) requisitions reviewed. In the first instance, two unordered tests were completed. In the second instance, three additional tests were added to the original order. In the third instance, a test was completed twice, once as part of a panel and again as an individual test. It appeared that the additional tests were ordered as the result of data input errors.

Considering the large volume of laboratory tests that are processed on a daily basis, the identified error rate was low. However, additional protection against data input errors may be possible through application edit functions. System edits can flag duplicate tests if already ordered as part of a panel or identify test combinations that are not logical.

Charges for tests not supported by a physician order are considered to be medically unnecessary, and therefore not billable to third party payers.

Management Corrective Actions:

1. The Laboratory Compliance Manager will implement a quality control process that selects a sample of test requisitions to review for accuracy on a periodic basis.

2. LIS IT will determine whether SoftLab edits could be programmed to identify orders with duplicate tests or illogical test combinations.

3. The Laboratory Compliance Manager will determine whether the six tests charged without an order were billed to payers, and if so, request that a refund be issued.

2. SoftLab Test Panels

Two custom test panels were inappropriately included in the SoftLab Clinical module.

We identified two custom test panels that were charged on 12 of 88 (11%) of the test requisitions reviewed. These panels were created upon department request in prior years and transferred into SoftLab from the previous LIS.

Laboratory test panels are groups of diagnostic tests that have been found to be the most cost-effective, sensitive and specific means for evaluating a particular organ, organ system, or identifying a disease process. CMS has authorized selected test panels[12], seven of which were included on test requisition forms and Epic laboratory order screens.

The 2009 and 2011 Annual Laboratory Compliance letters each state that only CMS authorized panels will be processed, and encourage physicians to order individual tests if all tests included in an approved panel are not medically necessary.

The continued use of custom panels was not consistent with the statements in the Annual Laboratory Compliance letters.

Management Corrective Actions:

1. The Director of Clinical Laboratories posted a memo on the Laboratory website, which stated that only CMS authorized panels would be processed.

2. The Laboratory Compliance Manager has removed the two custom panels from the SoftLab Clinical module.

3. Unidentified Ordering Physician

We noted that the ordering physician was not identified on three of 88 (3%) test requisitions reviewed.

Each of the three referenced requisitions was faxed to the Laboratory, and included the physician's phone number and address. They were not signed, and did not reference a physician identification number or a pager number. Therefore, the order was accessioned as physician "unknown."

[12] CMS-Approved Test Panels include: Acute Hepatitis Panel; Basic Metabolic Panel; Comprehensive Metabolic Panel; Electrolyte Panel; Hepatic Function Panel; Lipid Panel; Obstetric Panel; and Renal Function Panel.

Per CMS, it "is the responsibility of the clinical diagnostic laboratory… to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by the physician or NPP [non-physician practitioner].[13]" Should questions arise regarding the order, Laboratories must be able to contact the ordering provider. The Laboratory had not developed a policy requiring that non-UCSD affiliated physicians include standard information on a requisition such as the physician's state license number or some other identifier and a telephone or pager number.

Through further review it was determined that associated charges were matched at PFS with the appropriate physician information on the claim. However, this information should be collected at the point of accession to ensure that it is available for questions or contact during the testing process.

Because the Health Sciences Enterprise is expanding its operations to other geographic locations, the number of test requisitions submitted by outside physicians will likely increase in the future. Therefore it is vital that adequate ordering provider information be obtained to meet regulatory requirements, but not impede prompt specimen processing.

Management Correction Actions:

1. Laboratory management will post requisition completion guidelines for non-UCSDHS physicians on its public website.

2. The Laboratory Compliance Manager has collaborated with PFS to outline procedures designed to identify non-UCSDHS physicians at the point of order processing.

F. CPT Code Modifiers

SoftLab was not programmed to add the Common Procedural Terminology (CPT)[14] code modifiers required to ensure that charges include all required information, and are billed accurately.

Modifiers are appended to CPT codes to communicate additional information to payers. Modifiers 59 and 91 are frequently appended to Laboratory charges. Modifier 59 indicates a separate test on specimens obtained from multiple sites (for example, separate tests of skin biopsies obtained from the right and left arms). Modifier 91 indicates that one test repeated on the same date of service for the same patient are appropriate and supported by a physician order.

[13] "Medicare Program; Clinical Laboratory Fee Schedule: Signature on Requisition" 42 CFR Pt 410
[14] Codes in the American Medical Association's Current Procedural Terminology (CPT®) manual

Submitting charges without modifiers increases the possibility that payment will be denied as unsupported duplicate charges.

Management Corrective Action:

Laboratory management will collaborate with Revenue Cycle Administration and the Epic Team to (1) identify the current financial risk associated with charge denials due to the absence of laboratory CPT code modifiers; and (2) design a protocol for applying modifiers that will reduce the risk of denials or incorrect claims, prospectively. As part of this process, LIS IT will contact the vendor to determine whether Softlab tools that assist with applying modifiers have been developed.

G. Diagnosis Code Update

The SoftLab diagnosis code dictionary was not synchronized with FMS. As a result, some charges were rejected.

Diagnosis codes are published in the International Classification of Diseases, 9th Revision: Clinical Modification (ICD-9-CM) manual, maintained by the World Health Organization. As with CPT codes, ICD-9 codes are subject to periodic update. Revenue Cycle Administration applies ICD-9 code updates to FMS tables. During the SoftLab implementation process, updates to the SoftLab ICD-9 code dictionary were not identified as a critical task. Because updates were not timely, code variations between SoftLab and FMS arose which led to charges processed by SoftLab to be rejected by FMS. Additional effort was then needed to subsequently correct and re-enter these charges.

Diagnosis code updates should be a part of a routine application maintenance procedure to ensure that charges transferred from SoftLab to the billing office are efficiently processed.

Management Corrective Actions:

1. LIS IT updated the SoftLab ICD-9 code dictionary during audit fieldwork.

2. LIS IT will implement a formal ICD code update process to ensure that it occurs in conjunction with similar FMS updates.

H. Inaccurate Prices – Send-Out Tests

CDM prices for send-out tests were not accurate in some cases.

The Laboratories completed the majority of tests ordered by UCSDHS patient care units in-house. However, there are tests for which the volume is insufficient to maintain the specialized equipment needed to perform the tests. Tests not performed onsite are sent out to contracted reference laboratories for completion. These tests are referred to as "send-out tests" and this is a common industry practice.

Reference laboratory contracts help to maximize efficiency of Laboratory resources by eliminating the need to provide equipment and space for rare and low volume tests. Per California law (CA No. 98-104)(c): "It is also unlawful .... to charge additional charges for a clinical laboratory service that is not actually rendered by licensee..." Therefore, send-out tests are charged to patients at cost.

The use of send-out tests is varies by Laboratory. The following schedule lists the approximate number of send-out test in each Laboratory's CDM.

Laboratory Name	CDM Test Count	Number of Send-Out Tests	Lab Send - Out Ratio	Overall Send-Out Ratio
Blood Bank Lab - Hillcrest	77	31	40%	3%
Blood Bank Lab - Thornton	70	25	36%	3%
Cancer Center Lab	38	0	0%	0%
Clinical Lab - Hillcrest	302	5	2%	1%
Clinical Lab - Thornton	556	375	67%	41%
Immunogenetics & Transplant Lab	147	29	20%	3%
Medical Genetics Lab	131	14	11%	2%
Microbiology	301	95	32%	10%
Pathology - Hillcrest	108	2	2%	0%
Phlebotomy - Hillcrest	374	361	97%	40%
Point of Care	2	0	0%	0%
Total	2,027	906	45%	100%

The source of the data used in the analysis above is the CDM. In terms of actual Laboratory charge volume, [15] approximately 7% of charges were for send-out tests.

Send-out test prices were analyzed by selecting the 14 tests that ranked highest based on the number of tests ordered multiplied by the cost. The CDM price for each test was then compared to the price list for the reference laboratory that completes 80% of all send-out test activity. We found that ten tests in the sample

[15] Test statistics were derived for all laboratories from FMS Rev-6 reports for the period September 2010 to May 2011.

had a different prices on the CDM (and charged to the patient) than on the reference laboratory price list. We also noted that the ten tests with price variances were not associated with a special promotion or discount offered for a limited time by the reference laboratory. Therefore, to the extent that tests with discounted prices were included in the sample, the prices were accurate.

Periodic CDM review and adjustment of send-out test prices would help to ensure that the Laboratories do not overcharge or lose revenue for send-out tests performed.

Management Corrective Actions:

1. The Laboratory Manager updated CDM prices during the audit and will continue to perform a quarterly CDM contract price update.

2. The Laboratory Compliance Manager will review send-out test prices on a sample basis, and the process for performing this review will be documented in internal control procedures.

I. Paper Test Requisitions

Six of 88 paper test requisitions reviewed were incomplete or not in the standard format. In addition, certain patient care units routinely printed and/or faxed system generated orders to the Laboratories.

Office of Inspector General (OIG) Laboratory Compliance Program guidelines require that all laboratory tests performed by supported by a physician order. To ensure that complete information is available in the event of an internal or external review, Laboratory Administration must ensure that paper orders are complete, organized and stored for ease of access.

Completeness

The judgmental sample of 88 paper test requisitions selected for June 2011 was reviewed for completeness. We found that five (5%) did not include the information needed for a complete order. One was a printed copy of an Epic order that did not include a Hepatitis A antibody panel (HPAAB) that was accessioned in SoftLab. A second requisition was a SoftLab screen print that had a laboratory sticker attached, but did not include enough information to support the physician's order.

Printed Orders

Epic provides the functionality to prepare a test order that is electronically interfaced into SoftLab, eliminating the need to manage paper orders. However,

some departments have experienced problems with associating the Epic laboratory order with the appropriate patient number. For example, errors have occurred when a patient has tests ordered by different physicians practicing in different clinic locations. Selection of the correct patient number becomes more difficult when there are several active patient numbers, particularly if they have multiple patient numbers and the timing of their tests are overlapping. To avoid those errors, Laboratory test orders generated in Epic are routinely printed by some patient care units, including Transplant and Diabetes clinics, and are forwarded with the specimen to the Laboratory for processing. Laboratory staff used the paper Epic order to input the correct patient number into SoftLab when accessioning the specimen. Although this manual workaround has decreased the number of orders associated with an incorrect patient number, there is still some risk of manual input errors.

The ER entered test orders into the WebCharts system and they were printed in the laboratory. The Printed Epic and ER documents were collected and sent to storage with the paper requisitions used by non-Epic departments. The process for managing paper documents was resource intensive. Paper requisitions were filed alphabetically by patient. Approximately every three days, requisitions were moved from work areas to Laboratory file cabinets. Periodically, the file cabinets were emptied of the oldest requisitions, which were then boxed and transported to Iron Mountain long term storage.

While the use of the paper order document is an interim solution, additional focus on improving the Epic interface logic would help ensure that the correct patient number is transmitted to SoftLab for each order. Electronic orders are timely, and eliminate the need to store and track paper documents, saving staff time and reducing storage costs.

Management Corrective Actions:

1. Laboratory Administration and the Epic Team participated in a Lean Six Sigma evaluation designed to improve the management of electronic laboratory orders. Laboratory Administration will continue to identify and communicate concerns with electronic orders to the Epic Team and patient care areas, including Transplant Programs and Ambulatory Care to design and implement solutions.

2. Laboratory Administration will consider using an alternative solution to storing paper requisitions. For example, a dedicated fax server could be implemented to store faxed requisitions online for immediate access.

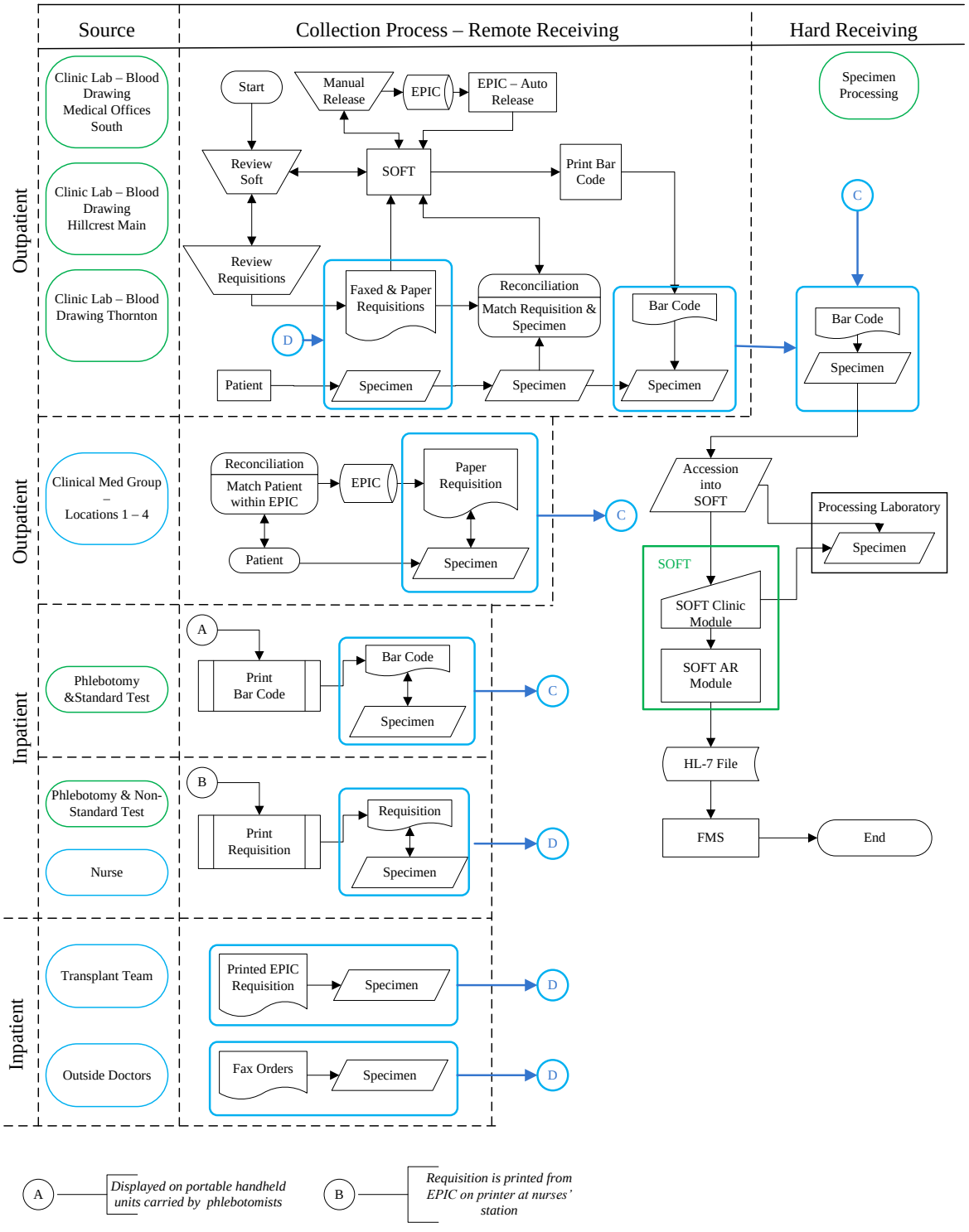
3. The Laboratory Compliance Manager will:

    a. Ensure that the five orders identified as incomplete are updated.

    b. Coordinate with the Health Sciences Compliance and Privacy Program Office to provide information and training to physicians and clinic staff on laboratory test order requirements.

4. The Epic ASAP system was implemented in the ER on June 4, 2012, which eliminated the generation of printed ER test orders.

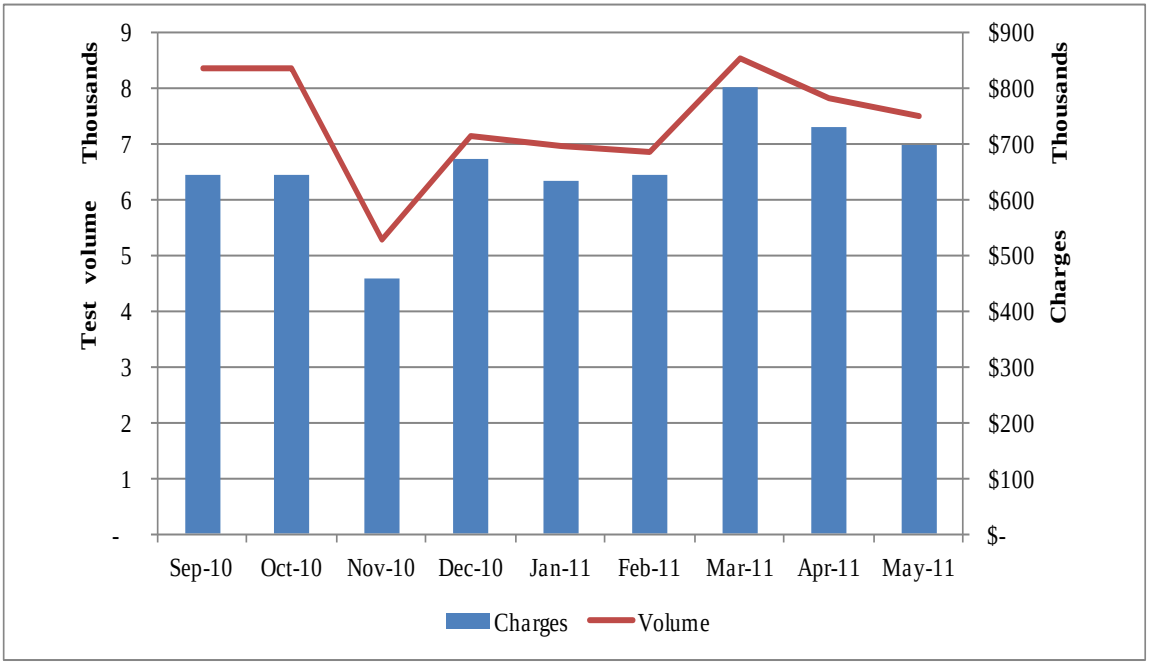
Attachment A - Laboratory Accession Process



Attachment B – Test Volume to Revenue Analysis - Selected Laboratories

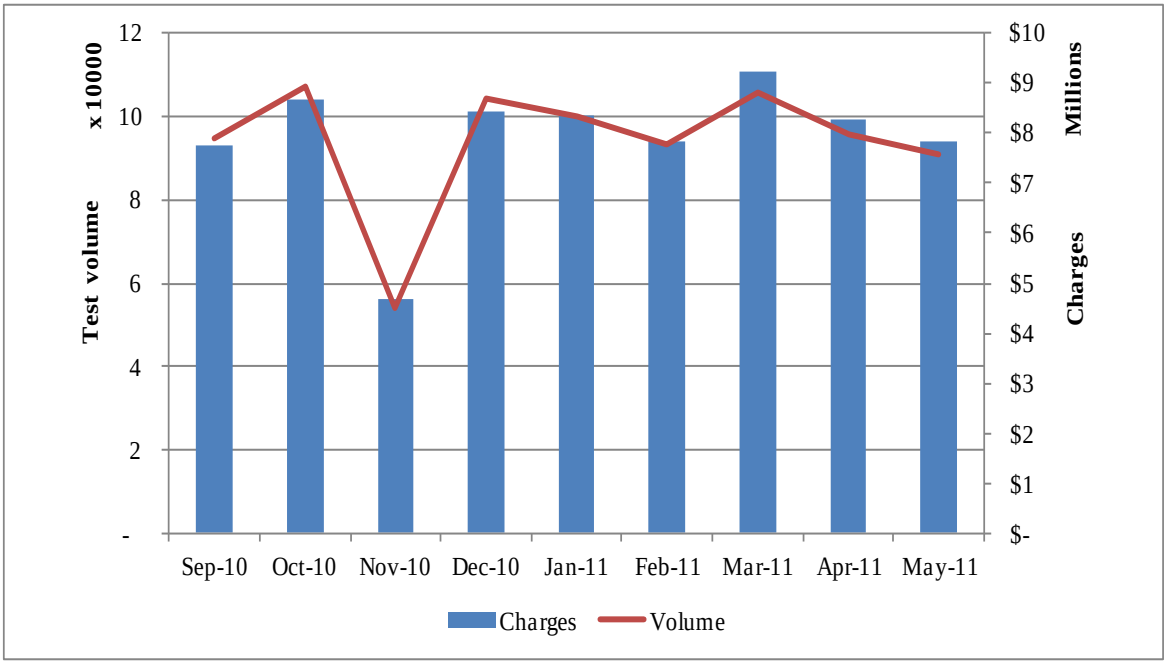
The SoftLab Phase I implementation on November 10, 2010 had different effects on each Laboratory based on the type of tests performed, tests prices, and the mix of in-house or send-out tests completed. The following charts were prepared using FMS tests and charges data for the period September 1, 2010 through May 31, 2011.

Cancer Center Laboratory



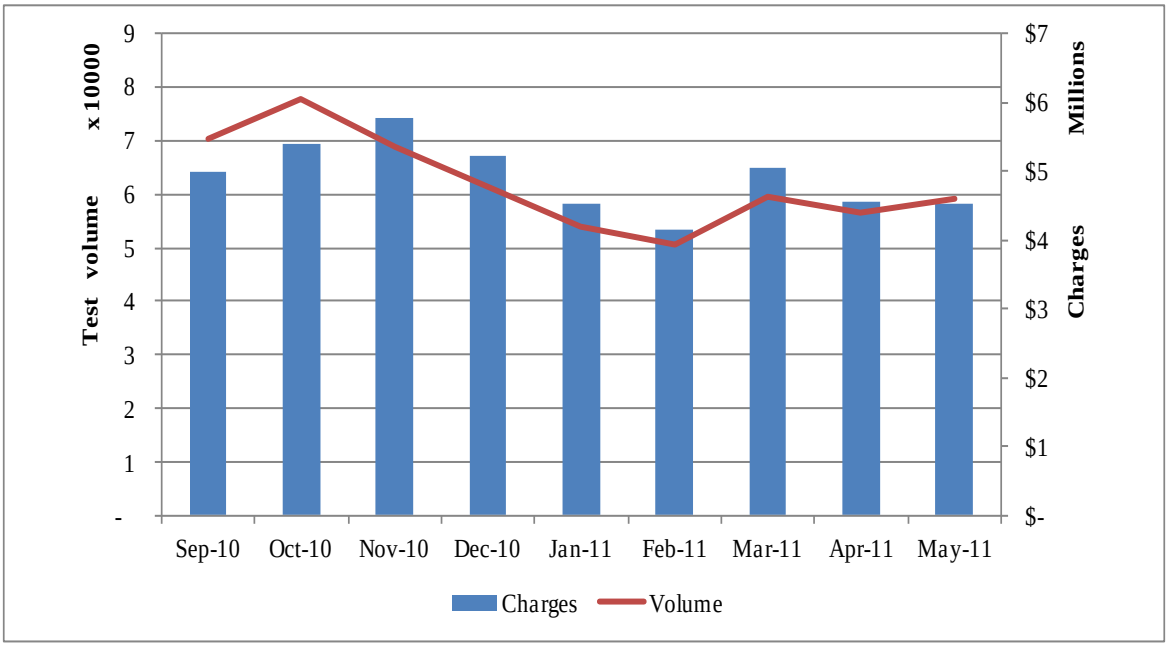
The Cancer Center Laboratory experienced a decrease of approximately 3,000 tests during November 2010. That volume is equivalent to approximately $231K in charges, which rebounded to prior levels in December 2010.

Hillcrest Clinical Laboratories



Hillcrest Laboratories test volume decreased by approximately 53,000 tests from October to November 2010. The decrease was equivalent to about one half the normal test volumes and was associated with charges totaling approximately $4M.

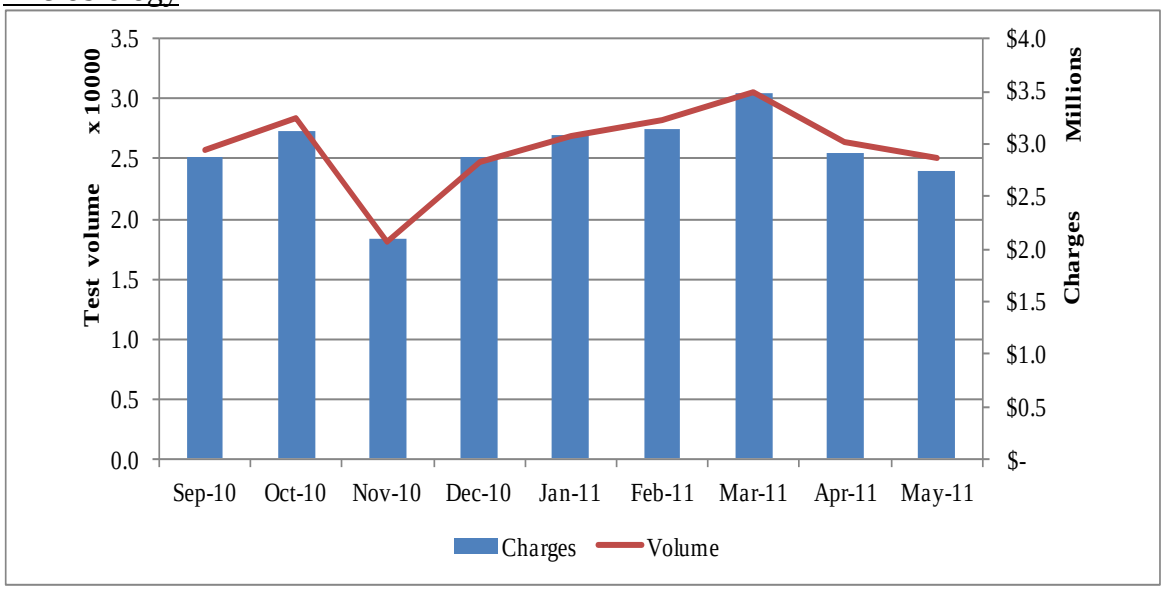
Thornton Clinical Laboratories



Although Thornton Laboratories did not experience a marked decrease in volume and charges during November 2010, a decline began in December 2010 and continued until

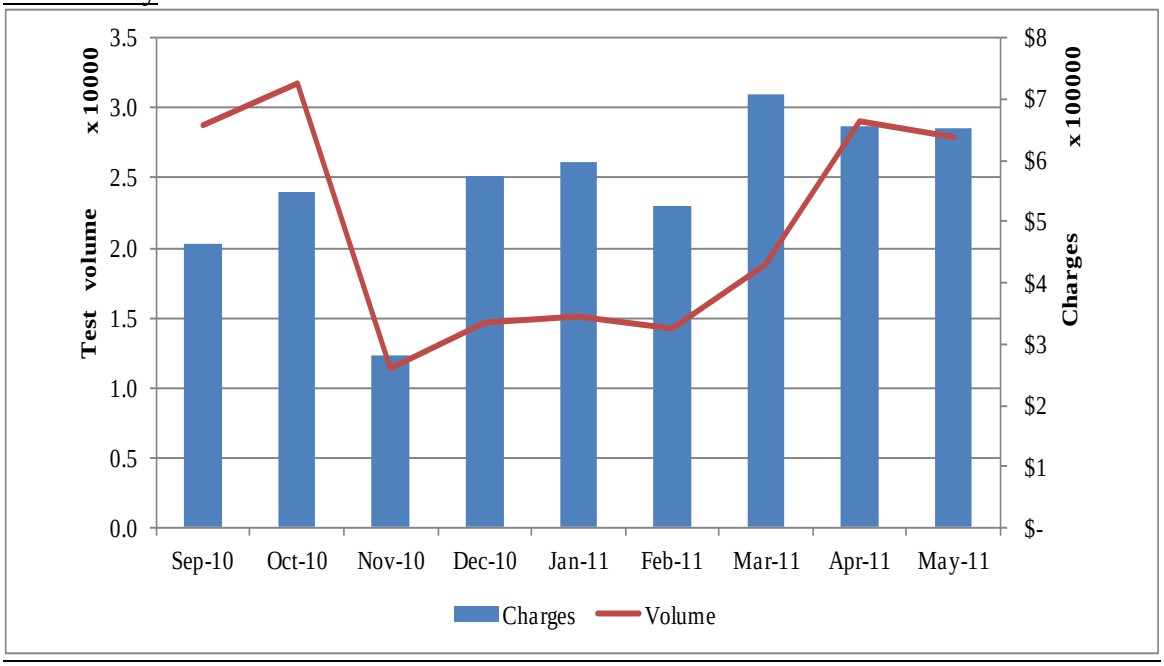
February 2011. The decline during this period is associated with approximately $1.6M in charges and approximately 18,000 tests.

Microbiology



Microbiology test volumes decreased by approximately 10,000 tests from October to November 2010. The decrease would be equivalent to charges totaling approximately $1M.

Phlebotomy



Phlebotomy test volumes decreased by approximately 20,400 tests from October to November 2011. The volume decrease was equivalent to charges totaling approximately

$266K. Charge volume returned to previous levels in April 2011.