Walking Tree Consultancy

Laboratory Information Management System (LIMS)

Business Requirement Specification

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Introduction

This document explains the Business Requirement Specification for the Lab Information Management Systems (LIMS), an important (optional) part of HaMSa.

LIMS is a class of software which handles receiving, processing and storing information generated by medical laboratory processes. These systems often interface with instruments and other information systems such as healthcare management solutions (HaMSa). LIMS' include haematology, Biochemistry, immunology, blood bank (Donor and Transfusion Management), surgical pathology, anatomical pathology and microbiology.
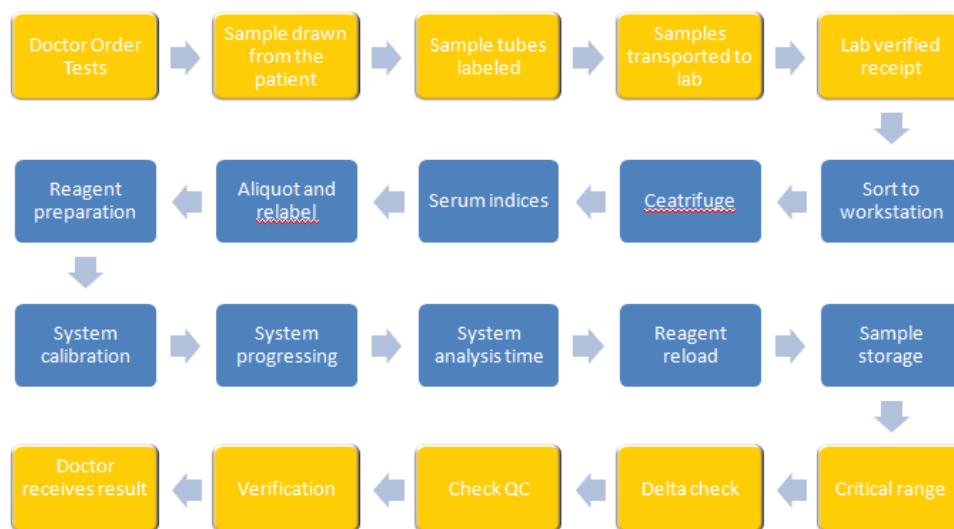
Typical lab test flow looks like as follows:

Figure 1: The process in orange will be targeted for automation

1. The items in orange are meant for implementation during this phase. Other items are excluded at this moment, because it is more useful for capturing research level data where we will have less than 1% customer looking for such features. Following are the definition and expectation out of the highlighted stages **Doctor Order Test** – is an order type which will be used by the doctor to prescribe a test for the inpatient. In case of outpatient, consultation detail will play similar role

2. **Sample Drawn From Patient** – Once patient decides to get the test done, sample needs to be collected from him / her. Either a laboratory staff (or their representative) will come to patient or patient will go to the laboratory and

give the sample. In case sample is found contaminated during the test then this process will be visited again and the next steps will continue

3. **Sample Tubes Labelled** – the tubes must be labelled correctly to relate them with the correct requisition and patient information.
    a. In future this labelling will be integrated with barcode or RFID to make the sample sorting and access process quicker. When the specimen is run on the machine, the bar code will be scanned and all information pertaining to patient demographics and nature of test will be read by the machine through the bar code and entered into the system.
4. **Sample Tubes Transported to Lab** – Many times the laboratory staff will come to patient and collect the sample. Sometimes laboratory may rely on certain sample collection centre to collect the sample. In such cases, the appropriately labelled sample needs to be transported safely and timely to the laboratory.
5. **Lab Verified Receipt** – Lab acknowledges the receipt of sample in the acceptable condition. If the sample is not acceptable then lab records that information as well and request for new sample collection.
6. **Critical Range** – check for critical range of test result and highlight them using the configured colour.
7. **Delta Check –** A delta check help in ensuring quality of the test. It compares current result of the lab test with previous result of the same patient for the same test using same method / reagent.
    a. Although some variation is expected, if there is a huge variation then it can be because of
        i. Some fault in testing or
        ii. Sudden change in patient's physical status
    b. In any scenario, the major variation requires conscious decision by the patient and / or doctor
8. **Check QC** – In this phase, laboratory performs various quality checks to ensure the quality of the test as per the quality control policy.
9. **Verification** – Once the technician says that the test has met all the quality and it can be passed on to the other stakeholders, it still has to pass through last quality gate, where an authorized individual verifies the test result and approve / disapprove the test result.
10. **Doctor Receives Result** – Finally test is marked as completed / rendered and test result is attached to the requisition order and the doctor's prescription / order. The printed test result is given to the patient.

Business Requirements

The laboratories, highlighted in red, are not yet documented in this BRS and it will not be part of Phase-1 of LIMS.

HLBR #		BRS	Phase
Labs supported by LIMS			
		Radiology Lab	
		Forensics	
		Clinical Trial Management	
		Haematology	1
		Pathology Lab	1
		Clinical Biochemistry	1
		Microbiology	1
		Serology	1
		Immunology	1
		Histopathology & Cytopathlogy	1
Entity Configuration			
	A	Managing business entities and their branch	1
		1. There may be multiple branches of a hospital – HaMSa should know how to allow multiple hospitals to exist in the same installation. This will be out of scope of LIMS. There must be a database table in HaMSa which will hold hospital information. HaMSa should have an API to return the hospital list.	
		2. There may be multiple labs within a hospital branch	
		a. while configuring the laboratory, select the first hospital in the hospital drop down list	
		b. Specify laboratory information	
		i. Laboratory Name	
		ii. Laboratory ID	
		iii. Laboratory Types	
		1. Some of the examples of laboratory types are	
		a. Microbiology	
		b. Biopsies	
		c. PET	
		d. Ultrasound	
		e. CT Scan	
		f. Ultrasound	
		g. ECG	
		2. The laboratory types will be configurable and inserted into the system through SQL scripts	
		iv. Correspondence Address	
		1. Street	
		2. Locality	
		3. City	
		4. State	
		5. Country	
		v. Contact Address	
		1. Email ID	
		2. Phone number	
		3. Mobile Number	
		4. Fax number	
		vi. How to reach from a known place	
		vii. Current Laboratory Operator ID	
		3. The lab may work independent of the hospital	
		a. The hospital selection must be optional	
		4. There may be multiple branches of a lab	
		a. There should be a way to specify parent laboratory name	
		5. There may be multiple sample collection point of the lab	
		a. Specify collection point information	
		i. Collection Point Name	

Comment [a2]: I think adding a reference to the source from where this information was prepared/derived would be good during the review and future references.

		ii. Collection Point Identifier
		iii. Correspondence Address
		    1. Street
		    2. Locality
		    3. City
		    4. State
		    5. Country
		iv. Contact person name
		v. Contact Address
		    1. Phone
		    2. Mobile
		    3. Email
		    4. Fax
		b. Associated with the laboratories
		    i. One collection point may be associated with multiple laboratories
		c. The system should also allow user to mention the areas covered through this collection points
		    i. One area may be covered by multiple collection point
		    ii. Areas will be the localities separated by comma	

	B	**Managing patient detail**
		1. Basic patient details like
		  o Name
		  o Gender
		  o Age
		  o Demographics
		  o Contact person's name
		  o Relationship with the contact person
		  o Contact detail like mail and phone numbers
		2. Over a period the system will manage test history of the patient in chronological order
		3. There will be an interface for the patient to access their test detail and download these test detail in PDF format
		  o Patient should be able to access the interfaces which are strictly meant for them.
		    ▪ Examples of such screens are
		    ▪ Patient Detail
		    ▪ Test Reports
		    ▪ Treatment history – HaMSa requirement
		    ▪ Appointment detail and appointment history – HaMSa requirement
		  o Patient MUST not be allowed to modify any detail
			1

	1	**Managing referring hospital / doctor**
		1. Basic doctor details like Name, Gender, Age, Qualification, Demographics, Contact detail, incentive (if override is needed) and associated hospital
		2. Managing internal doctor configuration
		3. Basic detail about the hospital specifically to be able to contact the right person in timely manner. For example following information will be useful
		  a. Hospital name
		  b. Demographic information
		  c. Contact detail
		  d. Google map integration to show a path between the hospital and the diagnostic centre (laboratory). This is specifically useful when laboratory is not inside the big hospital.
			1

	0	Managing Lab technician	1

		Managing corporate information – specifically for offers and promotions
		1. The company name, contact details, demographic information
		2. Discount details update
		  a. The price can be increased or decreased for a given corporate users
		  b. The price may be changed at a specific test level or for all the tests
			2

			c. Value should be mentioned in percentage of setup cost or absolute (will be rarely used) d. The system must store the effective from and effective to date	

Role-based access

	B		**Following roles would be supported** 1. Doctor 2. Technician 3. Receptionist 4. Patient 5. Lab Administrator 6. System Administrator 7. Management	1

Intended audience and user environment

	B		**HaMSa**
			1. (Configurable) If HaMSa is also installed in the same hospital and hospital wants to have integrated LIMS then the test result should be linked with the appointments and doctor orders
			2. There may be situation where patient may be treated by an outside doctor and he/she will come only for the laboratory test. In such cases, they would directly go to the billing counter and ask for the laboratory tests to be billed
			    a. The patient gets registered as direct patient (if they are not already registered with the hospital)
			    b. All the test will have a common requisition order
			    c. The test results will be grouped using the requisition order
			    d. Whenever patient comes to collect test result or logs-in into the system to view the test results, his / her results will be shown in chronological order, grouped on requisition order
			3. Different lab should be able to receive test orders from the
			    a. doctor order windows or
			    b. consultation detail
			    c. From OPD (Outpatient Department) billing counter
			        i. At the time of billing the patient, the counter should be able to print approximate waiting time
			        ii. After billing the OPD services, the lab should (configurable) book a slot for the patient
			        iii. If more than one lab tests needs to be done then there should be a rule which will allow scheduling and booking of available slots in different labs
			    d. Direct booking for the special patients (e.g. VIP, Emergency)
			        i. There should be a way to book the lab slot before OPD service billing itself. This facility may be granted to some of the special types of customer.
			4. Based on the appointment booking time, the system should be able to suggest the most suitable lab booking time for the patient. If there are more than one tests prescribed to the patient then the schedule must consider all the tests while calculating the slot availability
			    a. This should be just a suggestion and some authorized person must approve this booking
				1
				P2-3.c, 3.d, 4

			Swasth Jeevan (Configurable) 1. If a patient wants his/her test result on Swasth Jeevan then he/she must sign a consent with the laboratory and allow them to upload their test result 2. If the patient is not registered then it should first register the patient and then load the test result on SwasthJeevan 3. It should call Swasth Jeevan APIs to post patient test data on Swasth Jeevan	2
			It will be independently useful for Medical Pathology labs and Diagnostic centres	2
	B		**The product will have following business users and their roles** 1. Data entry operators 2. Reception operators 3. Technicians a. Results entry	1

Comment [a3]: I think for now, system shall have the capability to print the work orders for each department/lab and indicate the dependency (order in which the test need to be carried out), if any.

Comment [a4]: Remember that, initially, in 100% cases, the patient will not exist in SwasthJeevan. So before posting, the patient needs to be registered with SJ, internally, doc. Need to be posted, and then the URL, user id and password need to be printed on the customer invoice/receipt, which then they can make use of to check their reports online

b. Results entry approval
4. Doctor
   a. Test and report user
   b. Test and report designer
5. Management
   a. MIS reports
   b. Data Analysis
   c. Data Security
   d. Auditing
   e. Pre-plan test rates (service and package configuration)
6. Lab Administrator
7. System Administrator

Must provide access to multiple users concurrently, however, one user should have only one active login instance

| Test (Services) Configuration |

The tests would be configured as services
1. There will be a way to categorize service as Tests.
2. Using service type will be useful, as it will also allow us to configure other service categories like Radiology.
3. Test techniques and reagent
   a. A test can be performed using a given technique (this will be available only when a service is of type Tests).
      i. Some of the examples of techniques are
         1. Default Method
         2. CLIA Method
         3. Elisa
         4. RIA Method
         5. Western Blot Method
      ii. The techniques may be added as per the need of the laboratory
      iii. (Optional) For different techniques of the test, different activities need to be performed before reaching to a stage of concluding test result.
         1. This functionality would be made available through a configuration parameter value
         2. The system should allow setting up different activities for the successful execution of test
            a. Some of the steps may be mandatory and some of them may be optional
         3. While executing the tests
            a. the system would allow marking the activity as performed and it should also capture following detail
               i. User ID of the technician who has performed the activity
               ii. Time when that activity was performed
               iii. Remarks
            b. If at all there need to be any correction in the data of different activity then it must NOT be directly overwritten. We must maintain history of the original data and the personnel making that change.
   b. At a given time only one technique or reagent can be made as default and accordingly attributes will be used for report generation
   c. The test can be conducted using one or more techniques.
      i. There should be an interface to associate techniques with the test
      ii. The interface should allow modification of existing association
      iii. The association can be deleted, if none of the test was performed using the associated technique
      iv. If one or more test was already performed using the

Column reference: 1

3.a.iii, 3.f,3.g, 3.h, 5 - P2

associated technique then it can be moved into INACTIVE association status to indicate that this method is no longer applicable for this test

    d. A test can be performed using different reagents
        i. A reagent is a "substance or compound that is added to a system in order to bring about a chemical reaction or is added to see if a reaction occurs
        ii. Such a reaction is used to confirm the presence of another substance.
            1. Examples of such analytical reagents include sulphuric acid, hydrochloric acid, sodium hydroxide, Fehling's reagent, Millon's reagent, Tollens' reagent, Collins reagent, Fenton's reagent, and Grignard reagent. Refer to http://en.wikipedia.org/wiki/Category:Reagents_for_organic_chemistry for more examples about reagent.
        iii. There should be an interface to setup reagents.
    e. The test can be available for Male, Female or Both (default)
    f. The test will take an average amount of time – for example – if a patient goes through elbow X-ray, it may take 5 minutes, while an MRI scan may take 30 minutes.
        i. The knowledge of average time will be useful in scheduling the patient for the test
        ii. The average time should also include time required to make the equipment available for the next patient
    g. The test may have one or more pre-requisite. For example patient must come to laboratory empty stomach or patient must not take certain medicine before test.
    h. Time required for uploading and printing the test result for the patient. This will be helpful in synchronizing lab time with the consultation time
    i. A flag to indicate whether review of test results are required or not
        i. There may be certain tests where there is no need to review. For example X-ray
        ii. There may be certain tests where review may be required to ensure that the result documentation is correct as per the collected sample
            1. In such cases, the system should allow capturing information of technician who has crosschecked the result. Mainly following information needs to be captured
                a. User ID of the technician who has reviewed
                b. Date and time when he/she crosschecked
                c. Status of test result after checking
                    i. After crosschecking, the result may be marked COMPLETE
                    ii. ACCEPTABLE – with some remarks
                    iii. NOT_ACCEPTABLE with appropriate reason

4. There should be an interface to view and configure different samples to be collected from the patient
    a. The system should allow association of zero or more samples with the test
    b. The system should also indicate if the sample is mandatory for the test or not (default Yes)

5. A test may require zero or more legal documents to be signed by the patient. If the test requires any legal formalities to be completed then the system should allow association of the legal forms with the test
    a. The user should be able to attach scanned form and link them with the test detail

6. The tests would have certain attributes of type observation, numeric and text

value
    a.   There should be a way to define various test parameter categories.
        i.   Some of the example of such categories are:
           1.   Physical Examination
           2.   Chemical Examination
           3.   Microscopic Examination
           4.   Other Findings
    b.   There should be an interface to define new Parameter.
        i.   The Parameter – by default will have following information
           1.   Parameter Name
           2.   Parameter Type
           3.   Measuring Unit
           4.   Minimum and Maximum values and Normal Range text
           5.   Possible Values of the parameter (list of values)
        ii.   Some of the examples of test parameters are
           1.   Physical parameter categories
               a.   Specimen Colour
                   i.   Type – Normal Parameter
                  ii.   Possible observation values
                      1.   Pale Yellow
                      2.   Dark Yellow
                      3.   Greyish White
                      4.   Brown
                      5.   Dark Brown
                      6.   Straw
                      7.   Reddish
               b.   Appearance
               c.   Reaction
           2.   Chemical parameter categories
               a.   Albumin
               b.   Sugar
           3.   Microscopic parameter categories
               a.   Pus cells
               b.   Red cells
               c.   Epithelial cells
               d.   Crystals
               e.   Casts
    c.   There should be an interface to associate one or more test attributes with the test for the given method / reagent.
        i.   In addition to attribute value, there should be a way to capture
           1.   Comments of investigator / technician and
           2.   Automatically indicate whether the value is normal or not

	1	1. A service will be optionally associated with a service group 2. The system should support service group hierarchy	1
	1	A service may be in Concept, Active, Suspended and Expired status	1

Comment [AR7]: How will doctor use this information while assigning test to the patients?

1. A service will have an effective date and optional expiration date
2. A service can be suspended for a fixed or indefinite period
   a. When the service is suspended, the service will not be available for assignment and / or rendering
   b. The service suspension history must be captured
3. Once a service is expired, it will not be usable in future

	B	**Service/Test Assignment**	1

Service/Test Assignment
1. In order to assign a service (test) to the patient the service must be in active status
2. Once a service (test gets assigned to a patient, it goes through the lifecycle depicted in the below image

Assigned Service State Diagram

3.

		Service price and incentive history	2

Service price and incentive history
1. The system must maintain service price and incentive history. Following attributes must be part of every history entry
   a. Test Name
   b. Test price
   c. Price change date
   d. Effective from date
   e. Effective to date
   f. Doctor / hospital incentive
   g. Investigator incentive
   h. Rates applicable for (Whole Day (default), Day (6 AM to 10 PM, Configurable), Night)
   i. At some of the hospital, people charge more for the night as compared to day. In order to support such things, this will be useful

	B	**Test Price Update**	1

Test Price Update
1. The system should allow updating rates of the tests. It should allow update for
   a. All departments or selected departments
   b. All tests or selected tests of the selected departments
2. Rate can be incremented or decremented

		3. The amount can be specified in absolute or percentage of existing test price 4. It should allow user to indicate the effective date for the new rates 5. Any update must maintain corresponding test price history		

		Promotions & Offers
		1. There should be a way to configure promotional offers for
		    a. All the tests or
		    b. Selected tests
		2. Promotion would be effective for a period
		3. Promotion history needs to be persisted
		4. Promotional price (also known as special price) may be made available to certain category of patients, for example corporate patients or to the patients of preferred companies
			2	

Test Plan (Package) Configuration

B	1. One or more tests may be combined together to create a service package
	    a. There should be a way to define order in which test needs to be performed in that package
	2. A package will have an effective date and expiration date
	3. Same package name can be used again and again, while they must have different package identifier to ensure integrity of the rendered package
	    a. If a package with same name exist and its expiration date is set to null or some future date then it must be first expired on previous date of the effective date of the new package
	4. The system must provide ways to filter active as well as expired package
	5. The system should also allow creation of package, which will be effective in future
	6. Package price can be overridden at two levels
	    a. service level or
	    b. package level
	7. The discount can be absolute or percentage.
	    a. In case percentage amount is decided at the package level then first add the base price of all the included services and apply percentage calculation on the total amount.
	8. When a service (test) assigned to a patient is part of the package then there should be a package indicator to make it more explicit on the requisition order as well as the invoice
	9. A package can be in Concept, Published, Active, Suspended or Expired status
		1

	10. An assigned package can be in Requested, Rendered or Canceled status	

		Discount configuration on Packages	2
		1. The system should allow configuration of special rates for specific category of the patient	
		2. The system should allow corporate discounts, which may vary from company-to-company and service-to-service	
		a. There may be one standard discount for a company, which will be applicable if the discount is not explicitly overridden for a given service	
		b. There may be a laboratory level corporate discount which will be applicable across all the registered companies, unless it gets overridden for that company	
		3. Rates are automatically picked-up if the patient belongs to the specific category. Examples of categories are BHEL-Executives, Infosys-Corporate, Corporate, etc.	
		4. Whenever discounted rates are offered, they should be compared against the direct price and highlighted in different colors on the invoice	

Test Requisitions (written request or order)		

	M	1. Based on configuration, requisition number (service order number) can be automatically generated by the system or manually entered by the operator	1
		a. By default automatic generation will work	
		b. This number must be unique across the system	

	M	1. There should be an interface to add one or more test to the patient's requisition order	1
		2. The requisition should contain at least following:	
		a. Patient Information	
		i. Name	
		ii. Gender	
		iii. Date of birth	
		iv. Correspondence Address	
		1. Street	
		2. Locality	
		3. City	
		4. State	
		5. Country	
		v. Contact Details	
		1. Email ID	
		2. Phone number	
		3. Mobile Number	
		4. Fax Number	
		b. Doctor Information	
		i. Referring doctor/hospital name (specifically valid for direct patients)	
		ii. Prescribing doctor name	
		c. One or more Tests	
		i. Test Name	
		ii. Charges	
		iii. Test Expected Date & Time	

		d. Prescription Information
		    i. Attach prescription or
		    ii. Link to doctor's clinical prescription on appointment
		       consultation details – if the requisition is based on the
		       appointment with the internal doctor of the hospital
		e. Requisition notes	

	M	There should be a way to get requisition order from
		1. clinical prescription of doctor's consultation detail
		    a. The doctor may prescribe tests multiple times using the same
		       prescription (appointment number). However, often there will be
		       one requisition order (service order) per appointment
		2. test order of the doctor order for inpatient
			1

	M	There should be a way to configure referring partners (Hospitals, Doctors and Old patients) and their commissions/incentives	1
	M	If the requisition is coming through hand written prescription then there should be a way to scan the document and attach it with the requisition order in the system	1
	M	There should be different icons / colour coding to indicate requisitions in different status. A requisition can be in following status 1. CREATED – the requisition order has been created in the LIMS 2. CANCELLED – the order has been cancelled before being billed 3. BILLED – the order is billed 4. PAID – the order is paid 5. REFUNDED – the order was cancelled after payment 6. PARTREFUND – the order was cancelled after rendering one or more services within the paid requisition 7. PARTRENDER – the order has been partially rendered. At least one of the test is yet to be conducted 8. RENDERED – the order has been completely fulfilled	1

	M	Searching for Requisition Order
		1. The user should be able to search requisition order using following attributes
		    a. Patient ID
		    b. Reference Type (OPD, IPD, Direct, Daycare, Emergency)
		    c. Reference Number (Appointment Number, Patient Appointment Number, Daycare Number, Emergency Code)
		    d. Patient Name
		    e. Requisition From and To Date Range
		    f. Prescribing doctor's name
		    g. Prescribing doctor's ID
		    h. Test Status
		    i. Test (Service) Name
		    j. Requisition for period
		       i. Today
		       ii. Last week
		       iii. This month
		       iv. Last Month
		       v. Older than last month
		       vi. Next Month
		       vii. Later this year
		2. The search result will show following attributes
		    a. Requisition order number
		    b. Patient Name
		    c. Patient ID
		    d. Referring doctor name
		    e. Requisition Date
		    f. Requisition status
		    g. Total Charge
		3. User should be able to select one requisition order and view the requisition detail
		    a. The user should be able to generate bill for the unbilled requisition order
		       i. User must not allow addition of new tests into the billed requisition order
			1

Comment [AR8]: Scanning is out of scope. If the prescription is already scanned then it will allow attaching the scanned image.

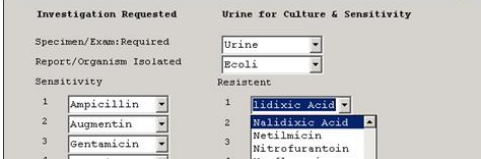|				

		b. The user should be able to mark the requisition order as PAID
		c. The user should be able to enter Test Result for a selected test of the requisition order
		d. The user should be able to change status of the test to
		    i. Sample Collected
		    ii. Test Performed
		    iii. Results Entered
		    iv. Results Approved. Internally, this should also link the test result with
		       1. the clinical prescription for an appointment
		       2. the doctor order for an inpatient
		       3. with patient ID for the direct patient
		    v. Rendered (refer to manage assigned service)
		e. Cancel one or more tests
		f. Refund money for the cancelled services (this is specifically useful for the OPD & Direct Patients)
		    i. In case a paid service is cancelled then system should show the amount to be refunded on the requisition detail window.	

	B	**Emergency order** 1. There should be a flag to indicate that this is an emergency order o For direct patient, it will be indicated on the requisition order window 2. If an order comes from Emergency ward then it should be automatically marked as urgent / emergency 3. The emergency rates will be applicable on the services with emergency order flag on	~~1~~ ~~(2)~~ ~~2P2~~

		Discounts on requisition
		1. If the discount is being given to a corporate patient then
		   a. his/her company detail and employee ID or some sort of reference number should be captured in the system
		   b. The requisition should be shown as discounted
			2

		Other charges
		1. There may be situations where patient may need to pay other charges apart from the regular charges already configured for the test. Some of the examples are:
		   a. The patient may want to get an extra X-ray slide from the laboratory
		   b. Patient wants to have an extra result copy
		   c. Patient dropped the sample collection container and he / she needs additional container
		2. There must be a reason specified for charging additional amount. For example – patient may need two copy of the report or two copy of the X-ray film
		3. In such cases, billing should take care of this as well and patient must receive this as a separate line item on their invoice (with reason printed as well)
			2

	M	**Editing Requisition** 1. The operator should be able to reset the requisition form during the creation time 2. The operator should be able to delete one or more tests ONLY when the requisition order is just in CREATED status	1

		Report collection
		1. Optionally system should capture mode for report delivery. For example
		   a. someone will come to collect the report
		   b. system is supposed to send an email
		   c. system will send the email as well as someone will come to collect the report
		   d. provide login access to patient so that he/she can view the test results related to his/her acquisition number
		2. It should also capture the information about the person authorized to collect the report and his/her relationship with the patient
			2

	M	**Showing requisition order**	1

Comment [a9]: This will be the default in Phase 1

			1. The system should show requisition order for a given
			    a. date, week, month, or all the requisitions
			    b. patient
			    c. doctor	

	M	**Origin of the requisition** 1. The system must show the origin of the requisition order. Also it should uniquely allow you to identify the context from the origin.	2

Assignment Source	Reference Type	Reference Number	Rationale
Outpatient	OPD	Appointment Number	We have two choices here. Patient ID or Appointment Number. Appointment number gives you exact idea about what services were rendered during which consultation. Hence, this number is used.
Inpatient	IPD	Patient Admission Request Number	For inpatient to avail services we must have an admission request number and all the orders are linked to that. Hence, this is the number which needs to be used.
Emergency	EMERGENCY	Emergency code	Every emergency patient will have an emergency code assigned to them.
Direct	DIRECT	Patient ID	Since we happen to register patient as well, with REGISTRATION TYPE as "DIRECT", so patient ID is the most suitable value to use.
Day Care	DAYCARE	Day Care Number	Similar to IPD (this needs to be updated at later stage)

Lab Test and Test Results

A	**Sample collection** There should be a way to define the samples to be collected for a given test 1. The test should be shown in different colour (configurable, default = RED), if the test status shows that sample has not been collected 2. If the sample was collected from the patient and it was contaminated then there should be a way to request for another sample a. The system must document a reason for requesting one more sample, specially what happened with the sample collected earlier	1

A	**Sample Transportation**
	1. Many times sample needs to be transported from one place to another place. The system should allow capturing of such transfer detail. It should at least store following information
	    a. The sample collection centre (also known as sample pick-up point), a place where sample is being collected from the patient
	        i. If the sample is being collected from the patient's home then the involved collection centre's detail should be captured
	    b. Lab details of the lab where the test is being performed
	2. There should be a way to indicate the temperature at which sample can be transported or should be stored. Transport of specimens takes place at following four temperatures
	    a. Frozen
	    b. Refrigerated (2-8°C)
	    c. 18-22°C
	    d. Room Temperature
		2

A	Following will be the typical workflow of a test 1. Requisition, Sample Collection (wherever applicable), Test and Research, Result Documentation, Result Approval, Result upload and communication to patient	1

	A	The history of test status transition should be captured	1

	A	**Test Report Designer**	1

1. There should be an interface for defining test report templates for a given test and technique or reagent
    a. The system should allow configuration of report's page style and page layout (e.g. Landscape, Portrait)
    b. A template may have following types of widget
        i. Label – showing fixed text
        ii. Text box, which will accept input from the investigator
        iii. Numeric text box, which allow us to build certain comparison logic
        iv. Drop down – showing list of possible values
            1. If there is any dependency – based on which the values should get filtered that we should be able to specify that as well
2. Refer to http://www.labtestsonline.org/inc/reports/SampleReport.html for a sample report

	A	There should be a template defined for different tests results	1

1. The template should contain the patient information like
    a. Name
    b. Age
    c. Gender
    d. Weight
    e. Height
2. The template should contain the doctor information like
    a. Doctor's name
    b. Doctor's speciality
3. The template should contain configurable attributes specific to the particular test and the method (or reagent) used for performing that test
    a. The normal and abnormal values for an attribute may vary based on personal attributes like gender, age, height, weight, etc.
4. Sometimes test results may use data from the previous test and based on that conclude certain things. For example – a patient went through urine test yesterday and he went through the test today as well. Some of the observations could be
    a. **Nothing grew on the agar in last 24 hours**
    b. Less than 10,000 organisms/ml (i.e. A small amount of bacteria was present)
5. The test result can be
    a. simple labels and values

    b. as well as complex attributes name and value combination being picked-up at run time

		c. The system should maintain different version of the template	

Intermediate Test Results
1. When a test is performed, the technician may need to perform test on one or more sample
2. The system should allow capturing of test results during every sampling of a given test
3. There will be standard method to use the test result after testing different sample (for the same test) and convert them into overall result, which will be analysed by the pathologist and converted into the final report, which will be used by the doctor responsible for treating the patient.
<<This section needs more elaboration>>

P2

Result entry
1. Information about all the investigators involved in particular test should be stored in the system
    a. Different tests may require different set of investigators
    b. One investigators may do various activity during the investigation
        i. System should allow capturing information about various activities during the test
        ii. The system should capture the records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period
2. The investigator should fill-up the template and save the test result. If the investigator has a privilege to save as well as approve test results then he the result should be automatically approved.
    a. If the investigator doesn't have approval privilege then the system should automatically figure out the approver of this result and the test result should be shown as pending approval on approver's dashboard.
3. If the investigator thinks that certain attribute is missing in the report template then he should be allowed to add new attributes.
    a. Investigator must have permission to alter report attributes
    b. If the investigator also has permission to alter report templates then he / she should be able to add the same attribute in existing template as well
4. The approver should see the saved test results on his/her dashboard. The approve and disapprove activity should be logged and test status should be accordingly updated. The approver should be able to do following:
    a. approve the result with some remarks
    b. disapprove the test results with appropriate reason
        i. This action should put the test result in draft status and the original author should be sent a notification about this.
        ii. The original author must review the test result and if needed collect the sample again and perform the test all over again
5. There should be an automatic flagging of test result values as normal/abnormal.
    a. For example highly abnormal value being shown in red, moderately abnormal value being shown in orange and remaining value being shown in default color
    b. The colour coding to indicate normal, moderately abnormal and highly abnormal will be configurable.
    c. Test result formula
        i. Neutrophils + Lymphocytes + Monocytes + Eosinophils = 100
6. All the test report (specially, if it has to be given to the patient) should have
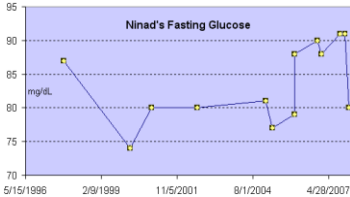
A

1

1.b.i,
1.b.ii –
P2

Comment [AR10]: Requires more clarity and it will not be included in Phase-1

		following attributes
		    a. A title (e.g. "Test Report – RBC Count");
		    b. The name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory
		    c. Unique identification of the test report (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report and a clear identification of the end of the test report or calibration certificate
		    d. The name and address of the patient
		    e. The test technique used
		    f. A description of, the condition of, and unambiguous identification of the item(s) tested
		    g. the date of receipt of the test item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test
		    h. The test results with, where appropriate, the units of measurement
		    i. The name(s), function(s) and electronic signature(s) of person(s) authorizing the test report or calibration certificate
		    j. where relevant, a statement to the effect that the results relate only to the items tested	

3.   Billing

	B	**OPD Billing**
		1. The services or packages will be first billed, then paid and then rendered
		2. The clerk at the OPD billing counter should be able to bill all the tests prescribed to the patient
		3. The clerk should be able to provide discounts if applicable
		    a. There may be situations, where a prescribing doctor may indicate that certain percentage of discount should be given to the patient. If the doctor is authorized to give the discount then corresponding discount should get applied on the bill and the doctor should be able to see that discount has been given to the patient on his/her recommendation.
		        i. (Optional configurable rule) If the discount amount is more than 5000 (a configurable value) then doctor should be asked to manually approve the discount
		4. At the time of billing, the clerk should be able to de-select zero or more tests and bill rest of the tests
		    a. After running the bill, the requisition details should show the actual billing status of the services.
		    ~~4.~~b. Unbilled services should be available for the billing. This will be useful in case patient want to avail that service next time
		5. After billing, the clerk should be able to cancel billing for one or more billed services as patient may decide not to get that test done
		    a. The payment made for the cancelled test should be refunded to the patient
		    b. The status of the service does not indicate that test process has already started. The service should be in one of the following status
		        i. CREATED
		        ii. BILLED
		        ~~c.~~iii. PAID
		    ~~b.~~c. If the service is part of the package then make sure that none of the service is rendered otherwise the services will not qualify for the cancellation
			1
			except (3)a

	B	**IPD Billing** 1. The services or packages will be first rendered, then billed and then paid a. The package will be considered eligible for billing if one or more service (test) in that package has been rendered. Also, such packages cannot be cancelled. 2. The services once rendered, should not be allowed to be cancelled	1

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	B	**Day Care billing** This will act similar to IPD billing	1
	B	**Emergency Billing** This will be similar to OPD billing, except that emergency rates will be applicable	1
	B	**Support for direct billing** Patient can directly come to the lab and take the test	1
Accounting support			
	M	Payments 1. Should accept different payment modes and capture all the relevant detail about the payments **2.** **Instalment plan should be supported for certain patient categories**	1 except items 2
	M	Deposits 1. If any test requires deposit then the system should allow deposit collection	1
Reports			
	B	The user should be able to print reports from the application	1
	B	Where ever graphical reports are possible, the system should enable a check box, which will indicate that the graphics is available for the report. Selecting the checkbox should allow user to see the same data in the graphical format. Default will always be textual format.	1

	B	MIS Reports
		1. Requisition
		    a. Following are the optional parameters for the requisition reports (where ever dropdown is available, it should allow selection of zero or more items)
		        i. Requisition from date and / or to date
		        ii. Requisition from number and / or to number
		        iii. Department dropdown
		        iv. Tests dropdown (If the department was selected then test should be automatically filtered)
		        v. Referred by hospitals list
		        vi. Referred by doctors list
		        vii. Company list
		        viii. Test status
		        ix. Test priority (only emergency checkbox)
		    b. Group By should be allowed on the search result (there should be a way to change group by and their level dynamically)
		        i. Test Name
		        ii. Department
		        iii. Patient Name
		        iv. Referred by
		        v. Date
		        vi. Company (specifically useful for corporate customers)
		        vii. Test status
		    c. Test search result should show following detail
		        i. Patient name
		        ii. Test requisition date
		        iii. Test performed date
		        iv. Date when test result was available for the patient
		        v. The date when patient collected the test result
		        vi. Total test charge
		        vii. Test status
		        viii. Associated department
		        ix. The main contact person for any information related to the test
		        x. Patient's referring hospital name
		        xi. Patient's referring doctor's name
		        xii. Test priority (Emergency for emergency patient otherwise blank)
		        xiii. Patient's company name (if the patient is a corporate customer)
		    d. Selecting particular test in the search result should enable user to view
		        i. Requisition Details
			1

		ii. Test detail and progress	
	B	**Account** 1. Patient Dues 2. Patient Concession 3. Patient Refunds 4. Receipt wise Collection 5. Doctor wise Collection 6. Investigator wise Incentive 7. Operator wise Collection **8.** Company wise Credit Payment	1
	B	Test Related 1. Department wise Tests 2. Test wise Techniques 3. Test wise Items 4. Test wise Parameters 5. Test Profiles 6. General Test Rate 7. Category/Company Test Rates 8. Test wise Company Rates 9. Doctor wise Test Referrals 10. Hospital wise Test Referrals	1
		Promotions 1. Reports to track increase in tests due to a promotion	2
		Others 1. Doctors 2. Hospitals 3. Hospital wise Doctors 4. Diagnosis List 5. Category wise Company 6. Locations	P2

> **Comment [AR11]:** Needs more elaboration

Analysis

	B	**Clinical Analysis**
		1. Two types of clinical analysis
		   a. Patients Test Results History Analysis
		     i. Following dimensions should be considered
		       1. Patient (one or more or all tests)
		       2. Test (one or more or all tests)
		       3. Date (date range)
		     ii. Examples
		
		       1.
		     iii.
		   b. Results Analysis
		     i. Following dimensions should be considered
		       1. Date (on requisition date)
		       2. Department (with inline hierarchy)
		         a. Test
		           i. Technique (or reagent)
		       3. Test Parameters
		2. should be supported based on
		   a. Departments
		   b. Dates
		   c. Test and attributes
			1

		d. Age e. Gender	

	B	1. Revenue analysis should be supported on
		    a. Patient demographics
		    b. Hospitals and doctors
			1

Dashboard			

	A	Every lab should have a dashboard which will show the tests scheduled in
		1. Details for every type of tests
		    a. Next one hour (expanded)
		    b. Rest of the day (collapsed)
		2. Just count for a particular test of the lab
		    a. Next day (Detail collapsed)
		    b. In next one week (Detail collapsed)
		    c. In next one month (Detail collapsed)
		    d. In next one year (Detail collapsed)
		3. The laboratory manager should have options of marking number of units as rendered and attach the test result with the requisition order
		4. The list of test results to be approved by the authorized doctor / technician
		    a. The complete list should be shown in expanded mode
		        i. He or she should be able to view detail of the test result
		            1. View test result window should have a button for the approver to mark the result as approved
		        ii. He/she should be able to select one or more results and approve them
		5. The list of reports that needs to be issued to the customer
		    a. Older than one month results to be shown based on date range search (initially, it will not have any detail)
		    b. Past one month results (Collapsed – with number of results yet to be given to the patient being shown)
		    c. Past week's list (collapsed – with number of results yet to be given to the patient being shown)
		    d. Today's list (expanded)_
		6. The lab technician should be able to see the list of tests to be performed by him / her in
		    a. Next one hour (expanded)
		    b. Rest of the day (collapsed)
		    c. During this week (collapsed)
		7. The lab technician should be able to see the list of test already performed by him / her in
		    a. Earlier this week (collapsed)
		    b. Earlier today (collapsed)
		    c. Last one hour (expanded)
			1

Inventory management of Labs			

	A	1. The test may have a need for one or more inventory items
		    a. The lab should be able to configure the reagent and other lab material suppliers detail, including the products and cost offered by them
		    b. There should be a way to define the list of items which will get consumed during every test and technique category
		    c. The system should automatically perform inventory control of that material
		2. The labs should be able to get their work order from the requisition order
		    a. If the lab is integrated with HaMSa then it should be able to drive work order from the related assigned services
		3. The lab should be able to relate the number of items to be consumed from inventory per test. If there are more items consumed than the standard set for the test then they should be able to adjust the inventory consumption related to that particular test. For example – if sample got contaminated or there was a spill over then there may be need to use more containers.
		    a. The inventory should get updated when the operator marks the test as rendered
			P2

		b. It is possible that there may be X unit of test prescribed to the patient, while the lab may be rendering only Y (<= X) number of units. The system should accordingly update the inventory and requisition detail 4. The lab may optionally be linked with a master inventory, which will be responsible for refilling the items	
Lab equipment management			

		1. The system should provide interface to add equipments in the system and associate it with the specific labs
		2. The system should capture details like manufacturer details and contact address, purchase date, next service date, last service date
		    a. The system should maintain complete service history
		    b. The system should also allow capturing of servicing request to the vendor and
		3. If the system crosses the service due date then operator's dashboard should show that
		    a. If the servicing date of equipment is nearing (say one week is left (it may be different for different equipment)
		4. Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:
		    a. the identity of the item of equipment and its software;
		    b. the manufacturer's name, type identification, and serial number or other unique identification;
		    c. checks that equipment complies with the specification
		    d. the current location, where appropriate;
		    e. the manufacturer's instructions, if available, or reference to their location;
		    f. dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
		    g. the maintenance plan, where appropriate, and maintenance carried out to date;
		    h. any damage, malfunction, modification or repair to the equipment
			2

Human Resource Management			
		The system should allow payroll support for the laboratory employees	2
Tools			
	M	**Settings** The system should allow updating system configuration to achieve different configurable features.	1
	M	**Backup & Archive** 1. The system should allow daily (or configurable period) backup of the laboratory data 2. The system should allow on demand archival of laboratory data a. Laboratory data will be archived based on requisition date. For example all the requisition older than two years will be archived and taken out of the transactional database	1
	M	**Restore** 1. In case system crashes or something goes wrong then the system should allow restoring the LIMS with previously stored data. 2. The system should capture the restore history	1
Swath Jeevan Integration			
		1. Swasth Jeevan allows healthcare providers to link the patient's treatment detail (also known as Continuity of Care Document (CCD)) with patient's Swasth Jeevan profile. 2. (Optional & Configurable) If the LIMS system is configured to upload the health record on swath Jeevan and patient has supplied his / her Swasth Jeevan id then the test results should get uploaded on Swasth Jeevan and it should get linked with patient's profile 3.	2

Swasth Jeevan Integration

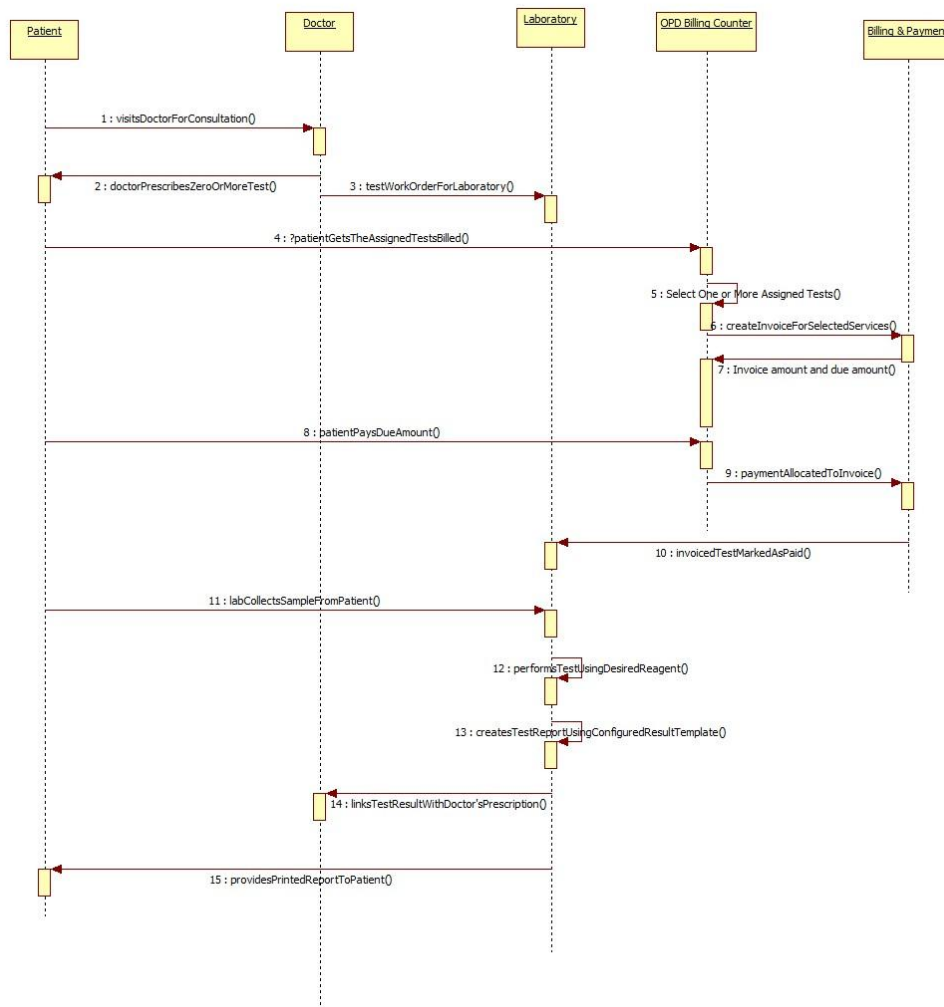| Value Added Services			

		1. The system should allow usage of barcode to label the samples
		  a. The same barcode should be used to feed the test result
		  b. Bar code should be linked with exact test for which the sample has been collected
		2. The system should allow configuration, which will allow user to see requisition data after the given date, even though old data may exist in the system
			2

Communication			
		Email support 1. The system should have inbuilt support for sending mails 2. The system should allow appropriate usage of context – for example recipient's name, gender, etc 3. The system should allow report delivery to patient through email attachment	2
Feedback & Complaints			
		1. The system should allow patient / attendant to provide feedback regarding the services provided by the laboratory 2. While providing feedback, the system should allow (optional) mentioning of requisition order number, patient / attendant name and contact detail 3. As per the complaint resolution policy of the laboratory, the patient should (optional) be optionally informed about the action on the complaint	2
Help Manual			
	M	We must have help for everything that we can do in the LIMS	1
Others			
		Franchisee management of the laboratory / diagnostic centre	2

Sequence Diagram

Lab Usage in OPD

Typically, patient visits a doctor. During the consultation, doctor prescribes zero or more lab tests and / or medicines to the patient. Many times doctors themselves would indicate that the tests are optional and sometimes they would emphasize on importance of test. Patient may decide to get the lab test done. He/she will go to the OPD billing counter and get the desired tests billed. Patient makes payment for the test and goes to the corresponding lab to get the test done. The lab collects sample from the patient and performs the required tests. The laboratory operators / investigators, creates test result reports in the desired format and attach the test result with the consultation report. The lab also provides printed lab report to the patient.

Patient	Doctor	Laboratory	OPD Billing Counter	Billing & Payment

1 : visitsDoctorForConsultation()

2 : doctorPrescribesZeroOrMoreTest()

3 : testWorkOrderForLaboratory()

4 : ?patientGetsTheAssignedTestsBilled()

5 : Select One or More Assigned Tests()

6 : createInvoiceForSelectedServices()

7 : Invoice amount and due amount()

8 : patientPaysDueAmount()

9 : paymentAllocatedToInvoice()

10 : invoicedTestMarkedAsPaid()

11 : labCollectsSampleFromPatient()

12 : performsTestUsingDesiredReagent()

13 : createsTestReportUsingConfiguredResultTemplate()

14 : linksTestResultWithDoctor'sPrescription()

15 : providesPrintedReportToPatient()

LAB Usage by IPD

The patient is admitted into a ward / nursing unit. Doctor issues a lab test order as part of the doctor order. The nurse raises this order with the laboratory. The test gets performed on the patient. The test result gets attached to the doctor order detail. The lab sends the test result to the appropriate nursing unit. After treatment – patient is ready to be discharged. The billing department bills all the charges to be paid by the patient. Patient makes payment. Patient gets NOC and he/she is ready to leave.
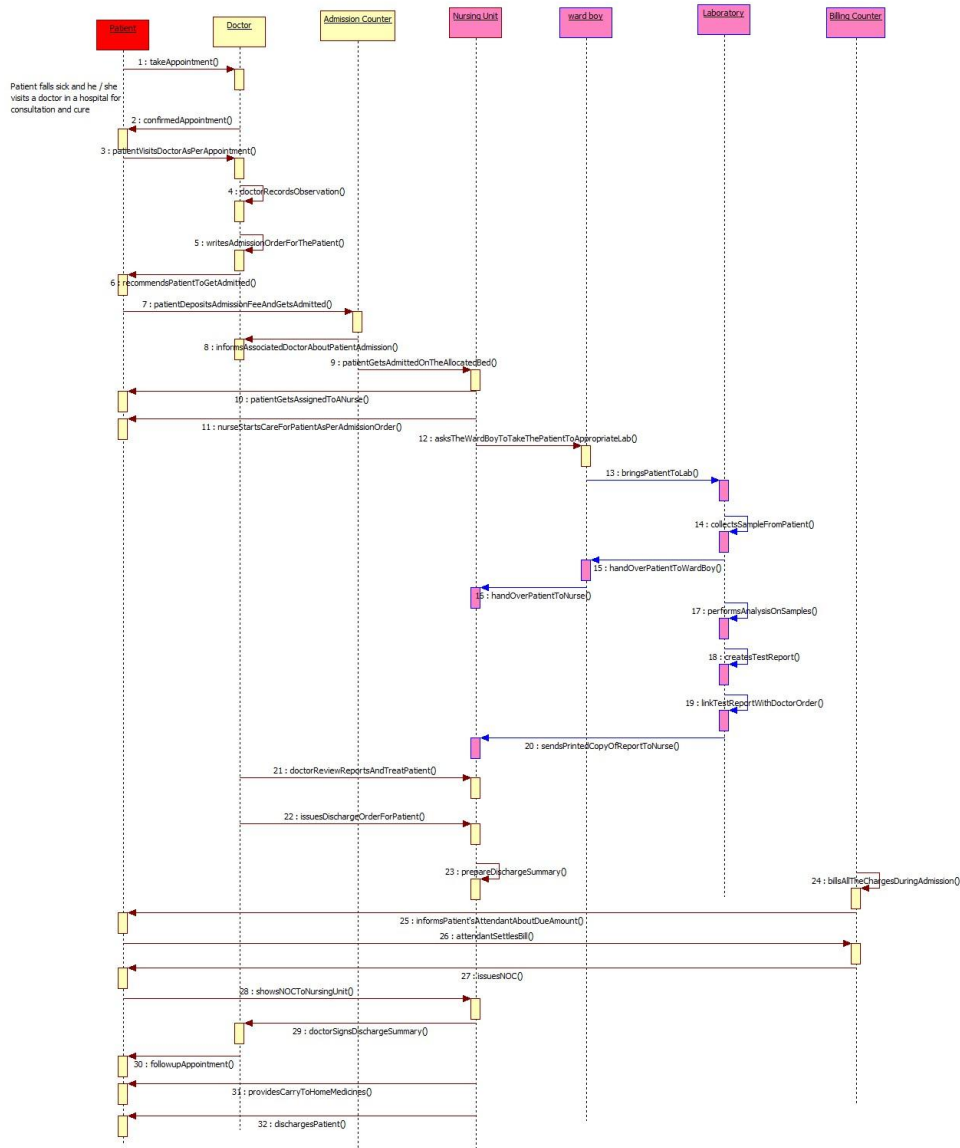
Direct Laboratory Service Usage

Assumption: The LIMS is installed inside the hospital in conjunction with HaMSa.

Many time patients will visit doctor outside the hospital and come to a recognized laboratory (in this case inside the hospital) for the tests. In such situation hospital will register the patient as a direct patient and continue with the billing followed by lab tests by specific labs.
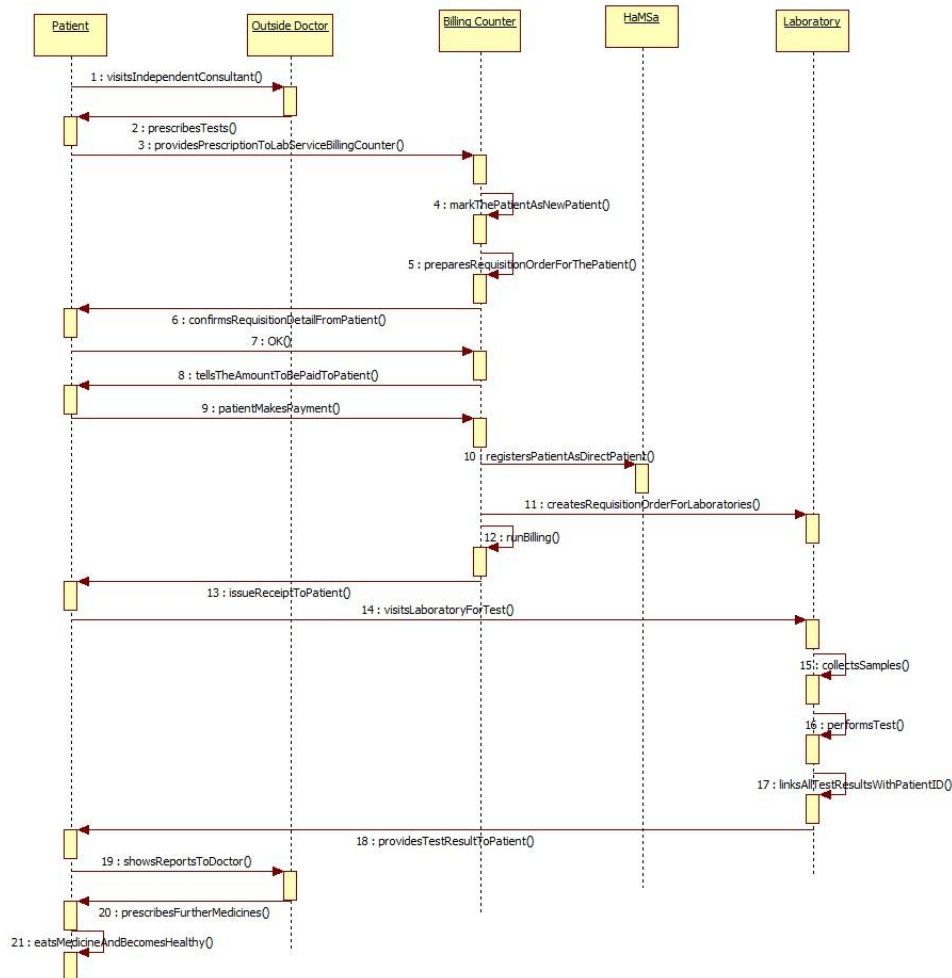
Stand Alone Laboratory

Not supported in current phase.

Additional things to be considered

1. Legal Aspects & Regulations
   a. Regulatory Standards
      1. ICH
      2. GXP
      3. ISO 9001
      4. ISO 15189
      5. CLIA
      6. HIPAA
      7. CAP
      8. 21 CFR Part 11
2. HL7 compliance

Document History

Date	Author	Change Description	Version
20/03/2010	Alok Ranjan	Initial Draft	Draft
08/04/2010	Alok Ranjan	Updated billing requirement to make it more explicit	V1.0

References

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