CENTRAL LABORATORY
COMPETENCY ASSESSMENT PLAN
(For One Year)

Laboratory Section (if applicable): _____

Assessment Method	Procedure, Method or Analyte	Date(s)
Monitoring the recording and reporting of test results		
Review of: intermediate test results or worksheets		
Review of: quality control records		
Review of: proficiency testing results		
Review of: preventative maintenance records		
Direct Observation of Test Performance:		
Direct Observation of Instrument QC:		
Assessment of Test Performance (Wet Sample):		
Assessment of Problem Solving Skills:		

Describe how you will ensure that the above assessments will take place.

Describe how you will ensure that assessments will take place in subsequent years.

POINT-OF-CARE TESTING
COMPETENCY ASSESSMENT PLAN
(For One Year)

Patient Care Unit: _____

Instrument or Test	Assessment Method*	Date(s)

* Assessment Methods:

1. "Blind" specimen (Assessment of Test Performance)
2. Direct Observation of Test Performance
3. Monitor QC performance (Record Review)
4. Written Testing (e.g. Problem Solving)

Describe how you will ensure that the above assessments will take place.

Describe how you will ensure that assessments will take place in subsequent years.

COMPETENCY ASSESSMENT SCHEDULE

Outpatient Clinic Laboratory

(The Every Test, Every Method, Every Tech, Every Year Schedule)

Technologist→	Technologist A					Technologist B					Technologist C				
Test, Analyte or Method→	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
1. Monitoring Recording and Reporting of Test Results	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
2. REVIEW OF:															
Intermediate Test Results or Worksheets	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Quality Control Records	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Proficiency Testing Results	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Preventative Maintenance Records	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
3. Direct Observation of Routine Test Performance	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
4. Direct Observation of Performance of Instrument Maintenance and Function Checks	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
5. Assessment of Test Performance	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
6. Assessment of Problem Solving Skills	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

COMPETENCY ASSESSMENT SCHEDULE

Outpatient Clinic Laboratory

(The Some Tests, Every Method, Every Tech, Every Year Schedule)

ASSESSMENT METHODS	PROCEDURE, METHOD OR TEST				
	1	2	3	4	5
1. Monitoring Recording and Reporting of Test Results	1 report/ employee	1 report/ employee	1 report/ employee	1 report/ employee	1 report/ employee
3. REVIEW OF:					
Intermediate Test Results or Worksheets	1 wrksht/ employee	1 wrksht/ employee	1 wrksht/ employee	1 wrksht/ employee	1 wrksht/ employee
Quality Control Records	1 record/ employee	1 record/ employee	1 record/ employee	1 record/ employee	1 record/ employee
Proficiency Testing Results	All	All	All	All	All
Preventative Maintenance Records	1 record/ employee	1 record/ employee	1 record/ employee	1 record/ employee	1 record/ employee
3. Direct Observation of Routine Test Performance	January				September
4. Direct Observation of Performance of Instrument Maintenance and Function Checks		March			
5. Assessment of Test Performance			May		
6. Assessment of Problem Solving Skills				July	

AGE SPECIFIC REFERENCE CHART			
Age	Safety	Communication	Psychosocial
Infant: 0-12 months	Maintain hand contact when crib rails are down	There are no means of verbal communication. Crying is a form of communication to display pain, discomfort or insecurity. Support parents in dealing with their anxiety because the infant perceives parental anxiety.	Major fears are separation and strangers. Attempt to minimize separation from parents.
Child: 1-3 years	Much more active and not always confined to bed. Curious and mobile with a short attention span. Security from medical supplies and safety from electrical outlets and sharps is important.	Prepare the child shortly before any procedure. Use simple explanations. May respond better to visual rather than spoken cues. Allow child to play with equipment as situation allows. Allow choices when possible, but do not ask for permission for procedure.	Major fears are separation and loss of control. Asserts independence and autonomy. Attached to security objects and toys.
Child: 3-5 years	Close observation is important to prevent injury. Security from medical supplies and safety from electrical outlets, sharps and hot substances is important.	Highly literal in their interpretation of words. Talk to child directly in simple language. Include family in explanations. Allow choice if one is available. Explain procedure shortly before it will occur. As situation allows, offer child a “job” during the procedure.	Learning to initiate activities and acquire direction and purpose. Striving to master their environment. Concerned about bodily injury, loss of control and the unknown. Able to live by rules.
Child: 6-11 years	Teach all patient safety rules for the patient with parent. Transport in wheel chair or on cart with side rails.	Provide straightforward explanations, allowing time for questions. Talk to child directly. Explain procedure in advance. Likes to stay involved and make decisions.	Curious and eager to learn. Prefers friends to family. Behavior is controlled by expectations, rules and regulations, and anticipation of blame or praise. Proud to show accomplishments
Adolescent: 12-18 years	An 18 year old can consent for own treatment or refusal of treatment. Can recognize danger. Transport as an adult.	Provide one-to-one communication and teaching to allow the adolescent time to ask questions that might not otherwise be asked. Provide high level involvement to give them a chance to make decisions in their care. Use	Interested and confused by own development. Concerned with physical appearance. Identity may be threatened by hospitalizations.

		adult vocabulary. Do not talk "down" to youth. Take time for explanations.	
AGE SPECIFIC REFERENCE CHART			
Age	Safety	Communication	Psychosocial
Adult: 19-45 years	Inform of safety policies.	Be supportive and honest. Recognize commitments of home and family; consider inconvenience of hospital stay.	Initiating a career, finding a mate, establishing a family. Begins to express concerns for health. Moves from dependency to responsibility. Often responsible for children and aging parents. Mental abilities reach their peak during the 20s.
Adult: 46-64 years	Inform of safety policies.	Focus on the positive and strengths, rather than weaknesses and limitations.	May experience “mid-life crisis”, major lifestyle adjustments, loss of parents or loved ones. Working up career ladder. Recognition of limitations. Adjustment to possibility of retirement. If children leave home may have “empty nest’ feeling.
Adult: 66-79 years	Keep environment safe: wheel locked o bed, side rails up if necessary, and proper lighting.	Provide privacy, but not social isolation. Due to decrease in senses, this age group may need frequent reinforcement. Repeat information, write information and instructions as needed. Involving family members can prove useful for these patients.	Adapting to change of social role and loss of significant others. Often entering retirement. Pursuing interests, hobbies, and community activities. Concern for health issues increase. Be aware of the patient’s right to be informed.
Geriatric: 80 and up	Older adults may be disoriented, hearing impaired or have decreased alertness because of medications and previous illness.	Encourage patients to avoid despair by expressing their feelings. Try to keep them positive. Instructions may need to be frequently repeated due to poor memory, vision or hearing ability. Written instructions often serve as a helpful tool for this age group.	Elderly adults want to remain in control of their care and their environment as much as possible. Their task in their own aging is to develop a sense of integrity and dignity. Motivation is an important component of performance.

COMPETENCY ASSESSMENT
OF NON-TESTING PERSONNEL

Assessment Method	Duties					
	Patient Prep.	Specimen Handling	Specimen Processing	Reportng Results	Instrmnt Maint.	**Other***
1. Monitoring Recording and Reporting of Test Results				x		
4. REVIEW OF:						
Intermediate Test Results or Worksheets						
Quality Control Records						
Proficiency Testing Results						
Preventative Maintenance Records						
3. Direct Observation of Routine Test Performance	x	x	x	x		
4. Direct Observation of Performance of Instrument Maintenance and Function Checks					x	
5. Assessment of Test Performance						
6. Assessment of Problem Solving Skills	x	x	x	x	x	x
Ability to Use SOP	x	x	x	x	x	x
Compliance with Safety Policies	x	x	x	x	x	x

*Duties not related to pre-analytic, analytic or post-analytic phases of testing

2001 - 02
STAFF COMPETENCY EVALUATION
PROGRESS CHART

Employee	Observe Testing 12/31/01	Observe Instrument Check 6/30/02	Problem Solving 6/30/02	Test Performance 6/30/02
Amy				
Ruby				
Peter				
Arvind				
Cecilia				
Sandra				
Glen				
Unfrena				
Gene				
Rommel				
Patricia				
Michael				
Mary Jo				
Larry				
Janice				

COMPETENCY EVALUATION PROGRAM

TRANSFUSION SERVICE

PURPOSE

Competency evaluation is the ongoing assessment of each employee's ability to perform work appropriately. For Transfusion Service staff this assessment includes several elements: direct observation of routine test performance, direct observation of performance of instrument maintenance and function checks, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, review of quality control records, review of proficiency testing results, review of preventative maintenance records, assessment of problem solving skills and assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. Competency evaluation will be included in each employee's semi-annual performance evaluation.

POLICIES

1. The Director is responsible for evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. Specific steps in this evaluation may be delegated to the manager or a technical specialist. Scheduling of the actual testing event selected will be assigned to the tested individual.
2. Assessment of competency is made based on adherence to blood bank policies and procedures.
3. Evaluation and documentation of the performance of transfusion service personnel will be done semiannually for all new employees (see procedure #902, New Employee Orientation). Thereafter, evaluations will be performed at least annually.
4. If test methodology or instrumentation changes, each individual will be reevaluated to include the use of the new test methodology or instrumentation.

MATERIALS

1. Direct Observation of Instrument Maintenance and Function Checks form
2. Direct Observation of Routine Test Performance form
3. Assessment of Problem Solving Skills form
4. Assessment of Test Performance form
5. Patient Worksheets
6. Donor Processing Worksheets
7. LIS Blood Bank Review printout
8. Quality Control records
9. Proficiency Testing records
10. Instrument Maintenance records
11. Immunohematologic Problem Worksheet

PROCEDURE

DIRECT OBSERVATION

Routine Test Performance

1. The forms for documenting competence to perform routine tests are distributed to testing personnel at the annual performance review and must be completed by the end of the interim performance review period.
2. Within this period request a Technical Specialist to directly observe performance of the listed procedure(s).

Instrument Maintenance and Function Checks

1. The forms for documenting this activity are distributed at the annual performance appraisal and must be completed by the end of the annual performance review period.
2. Within this period request a Technical Specialist, manager, or the Q.A. Coordinator to directly observe performance of the procedure selected by the Director.

ASSESSMENT OF PROBLEM SOLVING SKILLS

Assessment of problem solving skills is performed once during each year as scheduled by the technologist. Request an evaluation by attaching the Assessment of Problem Solving Skills form (distributed at the annual performance appraisal) to a completed Immunohematologic Problem Worksheet. The assessment is made by the Reference Laboratory Supervisor and documented on the form.

ASSESSMENT OF TEST PERFORMANCE

Performance of one or more routine blood bank tests is also assessed on a previously analyzed sample (without direct observation). This may be accomplished by selecting a Proficiency Testing sample or by requesting that a Technical Specialist select an internal, previously analyzed sample. The request is made by completing an Assessment of Test Performance form which is then reviewed by a Technical Specialist. The form is distributed at the annual performance appraisal and must be completed by the end of the annual performance review period.

SUPERVISORY REVIEWS

The competency of all blood bank staff is also evaluated in the regular review of patient and donor records by the manager, supervisor or technical specialist as assigned. This review is performed daily or for weekends and holidays the next working day. Any errors detected are corrected immediately and reported on an Internal Error Report form (see procedure #681). If corrective action is required this is documented on the form. See procedure #680, Supervisory Review of Blood Bank Results for a discussion of each review.

Monitoring The Recording and Reporting of Test Results

Includes the LIS generated "Blood Bank Review"

Review of Intermediate Test Results or Worksheets

Includes: Blood Bank Patient Worksheets
Immunohematologic Problem Worksheets
ABO/Rh Reconfirmation Records

Review of Proficiency Testing Results

CAP survey evaluations are reviewed by the director, manager and/or assistant manager. In addition the analyst(s) must also review, sign and date the evaluation. If unsatisfactory results are obtained the corrective action must be documented on the written evaluation.

Review of Preventative Maintenance Records

Review of Quality Control Records

Adopted			Reviewed			Reviewed		
Revised			Reviewed			Reviewed		
Revised			Reviewed			Reviewed		
Revised			Reviewed			Reviewed		

TECHNICAL COMPETENCY PROCESS/PROCEDURE

Purpose

To identify the procedures and plan for evaluating and maintaining the competency of the laboratory's technical staff in compliance with:

- The 1988 CLIA of Health Care Financing Administration of the Department of Health and Human Services
- JCAHO Accreditation Manuals for Hospitals (P.A. 6.2.2)
- CAP Inspection Guidelines (01.5550)

Procedure

ANNUAL TECHNICAL COMPETENCY REQUIREMENTS

The following tasks, which serve to evaluate and maintain competency, will be performed and documented annually by each employee.

#	TASK	DOCUMENTATION METHOD
1	Direct observation of routine test performance, including patient preparation, if applicable, specimen handling, processing and testing	This is documented on the DIRECT OBSERVATION OF ROUTINE PROCEDURE OR INSTRUMENT MAINTENANCE AND FUNCTION CHECKS form. The employee will file a copy of one observed procedure in the Technical Competency manual.
2	Monitoring the recording and reporting of test results	This is documented by the final report forms. The employee will file a copy of the final report form for one patient in the Technical Competency manual.
3	Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records	The intermediate forms, QC records, and preventative maintenance records document this. The employee will file a copy of one of these items in the Technical Competency manual.
4	Direct observation of performance of instrument maintenance and function checks	This is documented on the DIRECT OBSERVATION OF ROUTINE PROCEDURE OR INSTRUMENT MAINTENANCE AND FUNCTION CHECKS form. The employee will file a copy of one observed instrument maintenance in the Technical Competency manual.
5	Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples	All employees perform external proficiency testing annually. The employee will file a copy of the results in the Technical Competency manual.
6	Assessment of problem solving skills	Each employee will complete one problem solving exercise each year. The employee will file this in the Technical Competency manual. Each job classification has different criteria for the level of problem solving expected. Check the requirements of your job classification to determine the level of problem solving skill expected.

#	TASK	DOCUMENTATION METHOD
7	Age related competency	This is documented on the SPECIMEN PROCESSING LOG. Peripheral blood from children <1 yr. old have different cultures than adults and children >1 yr. old. The employee will file a copy of the SPECIMEN PROCESSING LOG, on which it is documented that the employee initiated correct cultures on a child < 1 yr. old, in the Technical Competency manual.
8	Meets laboratory continuing education requirements	This is documented on the CEU sheet for each employee. The employee will file a copy in the Technical Competency manual.
9	All technologists will read each new/revised procedure and participate in reviewing old procedures.	This is documented on the PROCEDURE REVIEW DOCUMENTATION FORM and filed in the SOP manual.
10	Meets all laboratory safety requirements	This is documented on the SAFETY REVIEW LOG. The employee will file a copy in the Technical Competency manual.

STAFF RESPONSIBILITIES FOR PERFORMING AND DOCUMENTING TECHNICAL COMPETENCY TASKS

STAFF	RESPONSIBILITIES
Technical Competency Designee This position will be rotated annualy among the Medical Technologist Specialists. A rotation will be from November to October. The designee may ask any Medical Technologist Specialist to observe his/her competency tasks	1. Prepare an agenda item for the November Staff Meeting to discuss the following year's competency plan; and after that meeting: a. Prepare a procedure and an instrument competency task checklist for the Direct Observation of Routine Procedure or Instrumentation Maintenance Function Checks b. Prepare a problem and solution for the Problem Solving Skills. 2. Provide employees with all appropriate forms by January 1. 3. Observe a procedure and instrument competency task for each employee
Employee	1. Complete the Employee Technical Competency Annual Checklist and file in the Technical Competency manual by December 31. 2. Arrange a procedure and instrument competency task observation by the Technical Competency Designee. 3. File a copy of one final report form in the Technical Competency manual 4. File a copy of an intermediate form, QC record or preventative maintenance record in the Technical Competency manual 5. Perform annual proficiency testing and file results in the Technical Competency manual 6. Complete a Problem Solving Skills form and file in the Technical Competency manual 7. Place a copy of the age related competency documentation in the Technical Competency manual 8. Attain and document 20 CEUs and file a copy in the Technical Competency manual 9. Read new/revised procedures and review old procedures as necessary and file documentation in the Technical Competency manual 10. Complete safety requirements and file a copy of the documentation in the Technical Competency manual
Supervisor	1. Review all Technical Competency Documentation for each employee and include in the Annual Performance Appraisal 2. Discuss corrective action with employees as necessary

Hennepin County Medical Center
Cytogenetics Laboratory
701 Park Ave., Mpls, MN 55415

EMPLOYEE TECHNICAL COMPETENCY
ANNUAL CHECKLIST

NAME:

TASK	FORM	COMPLETION DATE	SUPERVISOR REVIEW/DATE
Direct observation of routine test performance, including patient preparation, if applicable, specimen handling, processing and testing	Directob.doc		
Monitoring the recording and reporting of test results	Patient final report form		
Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records	QC records, intermediate form, preventative maintenance records		
Direct observation of performance of instrument maintenance and function checks	Directob.doc		
Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples	Proficiency records		
Assessment of problem solving skills	Problem.doc		
Age related competency	Specimen Processing Log		
Meets laboratory continuing education requirements	CEU form		
All technologists will read each new/revised procedure and participate in reviewing old procedures	Procedure Review Documentation Form		
Meets laboratory safety requirements	Safety Review Log		
Maintains current certification	Documentation of current certification		

Make a copy of this form for attachment to the Annual Performance Appraisal.

ANCILLARY LABORATORIES TECHNICAL COMPETENCY FORM

Section I: Patient Preparation and Phlebotomy

Name:_____ Date:

Score each item by marking P/F for pass or fail. If not done, mark as ND. Note any failures in the comments section at the end of this section, and document retraining needs on the Technical Competency Evaluation Form.

VENIPUNCTURES

_____ C 1. Obtain positive patient identification.
_____ N 2. Explain procedure to patient or guardian
_____ C 3. Assemble appropriate equipment and put on gloves.
_____ C 4. Position and inspect arm.
_____ C 5. Position tourniquet on upper arm and instruct patient to make a fist.
_____ C 6. Palpate vein and select a puncture site.
_____ C 7. Prepare area with alcohol, hold vein taut and insert needle, bevel up, at a 15° angle.
_____ C 8. Aspirate blood into appropriate tubes and mix as needed.
_____ C 9. Release tourniquet, withdraw needle and apply pressure with gauze flat.
_____ C 10. Inspect puncture site, apply gauze with tape if needed, or bandaid.
_____ C 11. Label specimen immediately with name, medical record number and date.
_____ C 12. Discard used equipment appropriately.
_____ C 13. Remove gloves and discard, and wash hands.
_____ N 14. Write initials, date and time drawn on test request form.

CAPILLARY PUNCTURES

_____ C 1. Obtain positive patient identification.
_____ N 2. Explain procedure to patient or guardian
_____ C 3. Assemble appropriate equipment and put on gloves.
_____ C 4. Inspect area and select a puncture site.
_____ C 5. Assess need of warm packs and use if needed.
_____ C 6. Prepare area with alcohol and wipe off with clean gauze flat.
_____ C 7. Firmly grasp heel or finger and apply lancet within appropriate area.
_____ C 8. Release pressure on heel or finger and wipe away the first drop of blood.
_____ C 9. Collect sample using pressure and releasing it.
_____ C 10. Fill tubes to appropriate levels and mix as needed.
_____ C 11. Apply pressure to puncture site with gauze flat.
_____ C 12. Inspect wound site and apply gauze with tape or bandaid if child or baby.
_____ C 13. Label specimen immediately with patient's name, medical record number and date.
_____ C 14. Discard used equipment appropriately.
_____ C 15. Remove gloves and wash hands.

C = Critical Task N = Noncritical Task

Section II: Specimen Handling and Processing

Name:_____ Date:

Score each item by marking P/F for pass or fail. If not done, mark as ND. Note any failures in the comments section at the end of this section, and document retraining needs on the Technical Competency Evaluation Form.

SPECIMEN HANDLING

_____ C 1. Labels specimens with date, patient name, medical record number and/or birth date.
_____ C 2. Completely and accurately fills our test request forms.
_____ C 3. Recognizes specimen identification errors and takes appropriate follow-up actions and documents them.
_____ C 4. Recognizes, documents and takes appropriate action when specimens are submitted to the laboratory in incorrect containers, in an untimely manner, or not according to temperature requirements.
_____ C 5. Stores specimens appropriately as required in a timely manner.
_____ C 6. Sorts, our over an puts specimens in Biohazard bags in the processing area in a neat and efficient manner.

SPECIMEN PROCESSING

_____ C 1. Operates the centrifuge properly and safely.
_____ C 2. Centrifuges specimens at the correct speed and time.
_____ C 3. Promptly and correctly cleans up breakages and spills in the centrifuge.
_____ C 4. Correctly performs and documents routine maintenance on the centrifuges.
_____ C 5. Handles all potentially infectious materials according to the Biohazard Policy in the Safety Manual.
_____ C 6. Prepares specimens to be sent to the main laboratory or reference laboratory according to their requirements.
_____ C 7. Correctly and completely logs all tests to be sent out.
_____ N 8. Maintains an adequate supply of specimen containers and blood drawing equipment.

COMMENTS:

Section Passed? (Yes, No) Retraining needed? (Yes, No)

Observer's signature:_____ Date:

DIRECT OBSERVATION OF
ROUTINE TEST PERFORMANCE

Employee Name: _____ Observer: _____ Date: _____

Instructions to the Observer

Observe the above named employee in the performance of the indicated procedure. Directly observe the employee perform each step of the procedure as listed in the table below. For each step of the procedure that conforms to the current immunology procedure place a check mark in the YES column below. If any step of the procedure is performed incorrectly place a check mark in the NO column and explain in the comments section below.

FTA IMMUNOFLUORESCENT TECHNIQUE (IFA)

Procedure Steps	**Yes**	**No**
Reviews incomplete list and makes corrective actions.		
Creates specific worksheets from the laboratory computer.		
Arranges samples according to worksheet order.		
Takes out appropriate reagents and samples from the refrigerator.		
Takes out appropriate IFA slides needed.		
Completes appropriate QC log sheet for each assay. Enters position of controls and patient samples into each slide diagram.		
Incubates IFA controls and samples in 56º waterbath.		
Pipettes proper diluents for each assay into separate 12x75 mm tubes. Properly labels tubes.		
Adds controls and samples. Makes appropriate dilutions.		
Adds controls and diluted patient samples into each well on specified slides		
Performs assays.		
Reads the IF QC slide the check the IFA microscope.		
Reads control and patient slides.		
Enters results on appropriate log sheets.		
Verifies QC values of each assay. Holds samples to be titered.		
Enters patient results into laboratory computer.		
Completes paperwork and files appropriately.		
Puts away reagents, supplies and samples. Cleans work area.		
Puts away patient samples.		
Submits log book to director, manager or designee for review.		

Comments:

Transfusion Service Observation of Routine Techniques for Technical Competency

All techs who work the bench in the Blood Bank laboratory will be responsible for requesting an "Official Observer" (see below) to directly observe their performance of at least the two selected routine Blood Bank procedures. (The procedures are selected by BB management). This activity will be documented on the attached form #2 and included in each tech's annual performance review. Submit all completed forms to your supervisor.
For this year, the procedures will be:

1. The Direct Antiglobulin Test (DAT), SOP 301.00. The observation will include:
   a. Check for adequate/proper labeling of sample tube.
   b. Check that type of specimen is correct.
   c. Cell suspension is properly prepared.
   d. Wash procedure is correct.
   e. Proper reagents are added correctly.
   f. Tests centrifuged, read, and incubated properly.
   g. Results recorded properly.
   h. Safety protocol followed.

2. Specimen update and history check, SOP 103.00 II. B & C and 104.01. The observation will include:
   a. Sample identification checked.
   b. Hollister form checked for signature and date by phlebotomist.
   c. In PR: Hollister ID# updated and Specimen Dates updated.
   d. IN PI: Checked by both name and medical record #. Read any special instruction and/or comments.
   e. check hard copy file.
   f. Check autologous/directed donation file.
   g. All appropriate information noted on Hollister form.

"Official Observers" include: xxxx xxxx, Pat Ellinger, zzz zzzzzzz and aaaa aaaaaaa.
"Official Observers" must be observed by Pat or Sue prior to observing others.

Transfusion Service
Hennepin County Medical Center
701 Park Avenue South
Minneapolis, MN 55415

FORM #2

Observation of Routine Patient Test Performance and Instrument Maintenance

Employee

The following routine patient test procedures and instrument maintenance have been directly observed:

Name of Procedure	Department	Observed by	Date	Conforms to SOP (Yes/No): explain No

Necessary remediation:

Date remediation completed:_____ Remediation documented by:

Any Hospital
Any Street
Any City, State, ZIP

Chemistry Department

MONITORING REPORTING AND RECORDING OF TEST RESULTS
or
REVIEW of PREVENTATIVE MAINTENANCE RECORDS

Year: _____

Employee	Work Station							Reviewed by:
	Centur	Gas	LX-20	Tecan	L:S	Lead	Stratus	Comments
Alexis								
Barry								
Candy								
Derek								
Elaine								
Frank								
Gina								
Horst								
Ina								
Jerry								
Kim								
Larry								
Mona								
Nat								
Oprah								
Perry								
Rita								
Sam								

COMPETENCY DOCUMENTATION
CYTOGENETICS LABORATORY
EVALUATION OF
CAP SURVEY PERFORMANCE

Employee Name

Instructions to the Evaluator

Evaluate the performance of the above named employee as to the accuracy of the results submitted for the assigned survey specimen and the process they used to achieve these results. Use the table below to indicate how well they performed each step of the procedures necessary to produce the desired result. For each step which conforms to the required CAP survey evaluation procedure and acceptable analysis, place a check mark in the YES column. If any step of the procedure is performed incorrectly, place a check mark in the NO column and explain in the comments section below.

CAP SURVEY PERFORMANCE

#	Procedure Steps	Yes	No
1	Review assigned specimen information & materials		
2	Cut appropriate karyotypes and label		
3	Determine type of abnormality (if present)		
4	Determine reason for special stains (if applicable)		
5	Enter modal chromosome number on form		
6	Using the Master Lists, enter sex chromosome designation on form		
7	Using the Master Lists, enter the designation for individual chromosome abnormalities on form		
8	Use the ISCN short form and enter an acceptable karyotype designation on form		
9	Answer interpretive questions as required		
10	Place all completed materials in folder provided by required due date		

Comments:

Observed by:_____ Title:_____ Date:

Evanston Hospital
2650 Ridge Avenue
Evanston, IL 60201

1993 - 94
DIRECT OBSERVATION OF INSTRUMENT MAINTENANCE AND FUNCTION CHECKS
Card Rotator Testing

Blood Bank
Transfusion Service

DUE ON OR BEFORE 6/30/94

Employee Name

Instructions to the Transfusion Service Employee

1. On or before the due date listed above schedule the following competency evaluation with a Technical Specialist, Manager or the QA Coordinator.
2. Review procedure #615, "Card Rotator Testing".
3. Perform the procedure and record your results on the appropriate form.
4. Your competence will be judged by how well you follow the procedures. You may refer to the written procedures during the performance of the procedure. If the evaluation of your performance is unsatisfactory you will be given instructions for corrective action.
5. If you find that the written procedure is unclear or missing necessary information, please make a note of it in the employee comments section.

Instructions to the Observer

1. Directly observe the employee perform each step of the procedure as listed in the table. For each step of the procedure which conforms to the current blood bank procedure place a check mark in the Yes column. If any step of the procedure is performed incorrectly place a check mark in the No column.
2. If all Yes boxes are checked, mark the Satisfactory box and sign and date the form. If a No box is checked, mark the Unsatisfactory box and describe the corrective action necessary to obtain a satisfactory rating.
3. Record your name, title and date on the Observed By: line.
4. Ask the employee to sign and date the form and submit it to the Manager or Director.

Procedure Steps	**Yes**	**No**
Allows rotator to warm up for 2 - 3 minutes		
Measures the RPMs		
Records the RPMs		
States the RPM criteria for acceptable performance		
Measures the diameter of rotation		
Records the rotation diameter		
States the rotation diameter criteria for acceptable performance		
Describes what to do if criteria are not met		

Evaluation of Test Performance ☐ Satisfactory ☐ Unsatisfactory

Corrective Action/Observer Comments:

Observed By:_____ Title:_____ Date:

Reviewed by Employee:_____ Date:

Employee Comments:

The Evanston Hospital
2650 Ridge Avenue
Evanston, IL 60201

2003
DIRECT OBSERVATION OF INSTRUMENT MAINTENANCE AND FUNCTION CHECKS

Employee Name: _____

Instructions to the Observer

Observe the above named employee in the performance of the indicated instrument maintenance or function check procedure. Directly observe the employee perform each step of the procedure as listed in the table below. For each step which conforms to the current Hematology procedure place a check mark in the Yes column. If any step of the procedure is performed incorrectly place a check mark in the No column and explain in the comments section below.

CELL DYN

Procedure Steps	**Yes**	**No**
Check levels and record lots/expiration date of reagents		
Power up, enter date, switch on optics lamp and printer		
Check pneumatic gauges, manometer, line voltage		
Check background and electronic checks. Print out and file.		
Cycle prime and observe instrument for proper cycling.		
Run 4C Plus controls and verify in control		
Sign maintenance calendar		

Comments:

Observed By:_____ Title:_____ Date:

TEST PERFORMANCE COMPETENCY EVALUATION
MICROBIOLOGY

Employee Name: _____

Interpretation of Germ Tube for Yeast Identification

Sample #	Employee Results	Supervisor Results	Agreement?

Comments:
Observed By: Title: Date:

Transfusion Service
Hennepin County Medical Center
701 Park Avenue South
Minneapolis, MN 55415

Name:
Date:
Score:
Passed?:

Blood Bank Competency Survey ("WET")

Blood Bank Procedures: the DAT, ABO/Rh, Antibody Screen and Crossmatch

Instructions

A. The samples are in a rack on the top shelf of the reagent refrigerator.

1. Sample #1: Perform the following procedures: DAT, ABO/Rh, Antibody Screen and Crossmatch (one unit of RBCs). Record results on the attached form.

2. Sample #2: Do not wash the cells or prepare a new cell suspension. Perform a DAT. Record results on the attached form.

B. Complete the survey and return it to Pat Ellinger or to your supervisor by October 20. If you are unable to complete the survey by this date, please speak to Pat or to your supervisor.

C. All employees who work in the Blood Bank Laboratory must complete the survey. Employees should work independently on the answers. The purpose of the survey is to assess and document the competency of all technologists who perform the procedures listed above in order to be in compliance with AABB, CAP, JCAHO and CLIA'88 standards and regulations.

D. There is a total of 50 points. Maximum points for correctly testing Sample #1 = 40 points: DAT = 5 points, ABO/Rh = 10 points, Antibody Screen = 15 points, Crossmatch = 5 points and interpretation = 5 points. Maximum points for correctly testing Sample #2 = 10 points: DAT = 5 points, interpretation = 5 points. Each employee will attain a least 70% of the total points. If a score of less than 70% (35 points) is obtained, additional questions will be created on the same subject(s) and/or the employee will have the opportunity to retest the samples.

E. If you find parts of these procedures that you feel are unclear or missing necessary information, please make a note of it on your survey and we will try to complete or clarify it.

Hematology Competency Testing

Body Fluid Differentials

Performance Expectations:

1. +/- 20% on normal fluid differentials.
2. Detection and/or identification of any blast or tumor cells.

Please include under comments the next steps you would follow if any abnormalities are found.

Employee name_____ Slide #

Differential	Result
PMN	
Lymph	
Mono	
Eos	
Baso	
Plasma	
Macrophages	
Mesothelials	
# Cells	

Comments:

Evaluation:

Title/Date

Technical Supervisor/Consultant Signature:

The Evanston Hospital
2650 Ridge Avenue
Evanston, IL 60201

Blood Bank
Transfusion Service

1994 - 95

ASSESSMENT OF TEST PERFORMANCE

Due on or before 6-30-95

Employee Name

Instructions to the Transfusion Service Employee

On or before the due date listed above schedule the following competency evaluation with a Technical Specialist. Assessment of your test performance can be done using your assigned proficiency testing sample or by requesting a previously analyzed, internal sample selected by a Technical Specialist.

You can determine whether you will be assigned a PT sample before the due date by referring to the CAP Survey Staff Rotation List at the front of the current CAP Surveys manual. CAP surveys are received in March, June, and October and there are at least 5 samples per survey.

If you are not assigned a PT sample (or if you prefer) you should request a previously analyzed sample. Whichever you choose, the assessment must be initiated by you by doing one of the following:

Proficiency Testing Sample

Complete the Proficiency Testing Sample gray box on the back of this form and submit it to the Assistant Manager or Manager with your completed proficiency testing worksheet(s).

Previously Analyzed Sample

1. Ask a Technical Specialist to select a previously analyzed sample for you to test.
2. Perform the tests indicated by the Technical Specialist and record them on a blood bank patient worksheet.
3. Complete the Blind Sample gray box on the back of this form and submit it with your blind sample worksheet directly to the Technical Specialist.

Instructions to the Assessor

Proficiency Testing

1. Retain this form along with the submitted worksheets until the survey evaluation is received (2 to 3 months).
2. Review the survey and record the requested specimen results on the appropriate line on this form.
3. Compare the survey results with those on the submitted worksheet and this form.
4. If the results are correct, mark the Satisfactory box on the back of this form. If the results are not correct, mark the Unsatisfactory box and describe the corrective action necessary to obtain a satisfactory rating. Place your name, title and date on the Assessed by: line on the back of this form. Ask the employee to sign and date the form and submit it to a Manager or Director.

Previously Analyzed Sample

1. Select a sample from the test tube rack of a recent day.
2. Determine which tests were performed on the sample by looking in the laboratory computer system. Make a note of the test results.
3. Remove a portion of the sample and place it in a tube labeled "Previously Analyzed Sample".
4. Instruct the technologist to perform one or more of the tests which have already been performed.
5. Record the previous test results, patient name and original date of testing in the appropriate spaces and compare the technologist's results with those from the computer.
6. If the results are correct, mark the Satisfactory box on the back of this form. If the results are not correct, mark the Unsatisfactory box and describe the corrective action necessary to obtain a satisfactory rating. Place your name, title and date on the Assessed by: line on the back of this form. Ask the employee to sign and date the form and submit it to a Manager or Director.

Proficiency Testing Sample

Survey Set and Specimen Number:_____ Date Tested:

Tests Performed:

Your Test Results:

Survey Evaluation Results:

Previously Analyzed Sample

Tests Performed:_____ Date Tested:

Test Results:

Previous Test Results:

Patient Name:_____ Original Date of Testing:

Assessment of Test Performance: ☐ Satisfactory ☐ Unsatisfactory

Corrective Action/Comments:

Assessed By:_____ Title:_____ Date:

Reviewed by Employee:_____ Date:

Reviewed by Director: _____ Date:

Evanston Hospital
Department of Pathology & Laboratory Medicine
Blood Bank

CAP SURVEY STAFF ROTATION LIST

EMPLOYEE	LAST SURVEY		MONTH/YEAR/SET#
Peter	10/93	C	
Amy	3/94	A	
Glen	3/94	A	
Cecilia	3/94	A	
Patricia	3/94	A	
Ruby	6/94	B	
Fren	6/94	B	
Michael	6/94	B	
Janice	6/94	B	
Gene	6/94	B	
Sandra	6/94	B	
Arvind	10/94	C	
Mary Jo	10/94	C	
Larry	10/94	C	
Rommel	10/94	C	

The Evanston Hospital
2650 Ridge Avenue
Evanston, IL 60201

Blood Bank
Transfusion Service

1995 - 96
ASSESSMENT OF
PROBLEM SOLVING SKILLS

DUE ON OR BEFORE 6/30/96

Employee Name

Instructions to the Transfusion Service Employee

After resolving an immunohematologic problem which you would like to submit for competency assessment, complete the top portion of this form, attach it to your completed Immunohematologic Problem Worksheet and submit it as usual.

Date of Workup:_____ Name of Patient:

Problem Solved:

Instructions to the Assessor

After reviewing the workup for completeness, proper recording of results and correct interpretation according to the policies and procedures of the blood bank determine if the problem was solved satisfactorily. If so, check the Satisfactory box and ask the employee to sign in the space indicated below. If the problem was not solved properly, check the Unsatisfactory box and make a recommendation for corrective action.

Assessment of Workup: ☐ Satisfactory ☐ Unsatisfactory

Corrective Action/Comments:

Assessed By:_____ Title:_____ Date:

Reviewed by Employee:_____ Date:

Reviewed by Director: _____ Date:

Any Hospital
Main Street
City, STATE Zip

Any Division
Laboratory

1995 - 96
ASSESSMENT OF
PROBLEM SOLVING SKILLS

DUE ON OR BEFORE 6/30/96

Employee Name:

Instructions to the Employee

Date:

After resolving a problem encountered in your daily work which you would like to submit for competency assessment, complete the top portion of this form and submit it to your supervisor.

Briefly Describe the Problem:

Describe What You Did To Solve the Problem:

Instructions to the Assessor

After reviewing the above for completeness and compliance with laboratory policies and procedures determine if the problem was solved satisfactorily. If so, check the Satisfactory box and ask the employee to sign in the space indicated below. If the problem was not solved properly, check the Unsatisfactory box and make a recommendation for corrective action.

Assessment of Workup: ☐ Satisfactory ☐ Unsatisfactory

Corrective Action/Comments:

Assessed By:_____ Title:_____ Date:

Reviewed by Employee:_____ Date:

Reviewed by Director: _____ Date:

Transfusion Service
Hennepin County Medical Center
701 Park Avenue South
Minneapolis, MN 55415

Name:
Date:
Score:
Passed?:

Blood Bank Competency Survey ("DRY")

Tissue Bank and Blood Bank Procedures: Ordering and Issuing TB products, TRAP Study, Washing Salvaged Blood, Preparing and Issuing Derivatives

Instructions

A. Answer the following questions by referring to the following revised Transfusion Service procedures (some procedures may still be in the blue "new Procedures for Review" book). Where requested, record the procedure number and the section (or procedure name and page number) where you found the correct answer. For example, 102.00 I.A..

B. Complete the survey and return it to Pat Ellinger or to your supervisor by January 20. If you are unable to complete the survey by this date, please speak to Pat or to your supervisor.

C. All employees who work in the Blood Bank Laboratory must complete the survey. Employees should work independently on the answers. The purpose of the survey is to increase your familiarity with updated procedures and their location for times when there may not be anyone else around to consult.

D. There is a total of 50 points. The number of points for each question is noted in the left column. Each employee will attain a least 70% of the questions and reference numbers correctly. If a score of less than 70% (35 points) is obtained, additional questions will be created on the same subject(s) and/or the employee will have the opportunity to correct the answers.

E. If you find parts of these procedures that you feel are unclear or missing necessary information, please make a note of it on your survey and we will try to complete or clarify it.

Blood Bank Competency Survey

Points

3 1. An Operating Room staff member has requested a 30cc bottle of cancellous chips. Finish completing the Release Form with whatever information is missing.

Procedure Manual Location

3 2. List the phone numbers you should call when placing an order with Red Cross for frozen or freeze-dried bone:

a. 08:00 - 16:00

b. after 16:00

Procedure Manual Location

11 3. Which items of Personal Protective Equipment are the minimum requirements to protect the health care worker from exposure to blood band body fluids?

a. Mashing a Clot

b. Thawing Frozen Products

c. Cleaning Up Spills

d. Reconstituting Products

e. Typing Units

f. Issuing Units

Where Did You Find This Information?

7 4. Based on the information provided by the University of Minnesota:

a. What does TRAP stand for?

b. How will we know when we have a new patient enrolled in the TRAP study?

WRITTEN EXAM QUESTIONS

Type of Test Question	Advantages	Disadvantages
Essay	Easy to construct Little opportunity for guessing Indicates ability to synthesize and analyze	Time consuming to score Difficult to obtain objectivity
Short Answer	Easy to score Allows more specific testing	Moderately difficult to construct
True/False	Easy to score	Difficult to construct 50/50 chance of guessing right answer
Multiple Choice	Easy to score Can be used with large groups	Very difficult to construct Correct answers can be guessed

Guidelines

Essay/Short Answer
- Requires clear instructions
- Requires a scoring guide that includes everything expected in the answer as well as distribution of credit.

True/False
- Construct short and easy to read statements
- Avoid double negative statements:
  - *Poor*: None of the white blood cells on the slide are not lymphocytes.
  - *Better*: All of the white blood cell on the slide are lymphocytes
- Items must be 100% true or 100% false
- Responses should be circled or checked, not written
- Include even distribution of true and false items

WRITTEN EXAM QUESTIONS

Multiple Choice

- Avoid negatively stated questions or statements:

  Poor: Which of the following antibodies does not react at 37°C?

  Better: Which of the following antibodies react on immediate spin and after room temperature incubation?
- Make the grammar consistent in the question and responses.
- Include only essential information in the question or statement
- Avoid absolute wording such as “always” or “never”.
- Address only one content area per item.
- When more than one response may be considered correct, the question must ask for the best answer.
- Include words in the question that would otherwise be repeated in every response.
- Avoid the distractors (wrong responses) “all of the above” and “none of the above”.
- Scatter answers evenly over the order of responses (25% a, 25% b, 25% c, 25% d).
- Make distractors parallel in form, length, and content:

AGE SPECIFIC COMPETENCY ASSESSMENTS
Phlebotomy Department

Infant: 0-12 months

Direct Observations: Never leaves infant unattended if crib rails are not up or present
Allows parent or guardian to stay with child

Problem Solving: Infants are fairly immobile and do not need monitoring when placed on a bed or a phlebotomy table. True or False

Child: 1-3 years

Direct Observations: Explains procedure to child shortly before beginning
Shows child equipment and allows her to play with it as the situation allows
Does not ask child for permission to perform procedure

Problem Solving: Because parents can be over-protective of their young children and interfere with needed procedures, they should not be allowed to stay with the child. True or False

Child: 3-5 years

Direct Observations: Ensures that phlebotomy area is safe by closing drawers and cabinets, making sharps containers inaccessible and covering electrical outlets
Explains procedure shortly before beginning

Problem Solving: A 3 – 5 year old is beginning to take control of his environment. In order to allow him some control over the phlebotomy one could give him a "job" to do such as:
a. holding or unwrapping the band-aid
b. disinfecting the puncture site
c. re-capping the needle

Child: 6-11 years

Direct Observations: Explains procedure and asks child if he has questions
Speaks directly to child

Problem Solving: Children 6 – 11 years old can recognize right and wrong as well as cause and effect. The best way to explain the procedure to a child of this age is to:
a. use puppets to act out the procedure
b. use general terms but do not reveal equipment
c. use specific terms and demonstrate equipment

AGE SPECIFIC COMPETENCY ASSESSMENTS
Phlebotomy Department

Adolescent: 12-18 years

Direct Observations: Uses adult vocabulary
Takes time for explanations

Problem Solving: Adolescents (12-18 yrs.) are concerned about privacy. True or False

Adult: 19-64 years

Direct Observations: No specific age concerns for phlebotomy

Problem Solving: Most 19 – 64 year old adults, who are balancing work and family demands, have plenty of time to wait in the outpatient phlebotomy department before undergoing their phlebotomy procedure. True or False.

Adult: 66-79 years and Geriatric: 80 and up

Direct Observations: Provides assistance if needed for movement, prevents falls
Speaks slowly, deliberately and looks directly at patient
Manipulatse arms using palm instead of fingers
Exercises care in application of tourniquet
Applies tape and band-aids sparingly

Problem Solving: Adults 66 and older may have sensitive skin. Because of this the following procedures should be followed:

a. Use the palm of your hand, rather than your fingers, to manipulate their arms
b. Carefully apply the tourniquet
c. Use tape and band-aids sparingly
d. all of the above

Due to certain conditions or illnesses that can affect the geriatric patient (80 years and up) certain practices should be followed. From the following columns, match the condition with the appropriate behavior

a. hard of hearing
b. poor vision
c. decreased mobility and stability

Provide large print reading material ___
Offer to assist them to a chair ___
Speak slowly and clearly ___

Glucose Monitoring Using SureStepPro For Adult Patients

Employee Name _____ Date _____

Instructions to the Observer

Observe the above named employee in the performance of the indicated procedure. Directly observe the employee perform each step of the procedure as listed in the table below. For each step that conforms to the current written procedure place a check mark in the Yes column. If any step of the procedure is performed incorrectly place a check mark in the No column and explain in the comments section below.

Procedure Steps	Yes	No
Turns on the glucose meter		
Checks the battery and memory status bars		
Demonstrates changing the battery		
Demonstrates performing a data transfer session		
Washes hands and dons gloves		
Selects patient test from the menu		
Enters operator ID		
Selects strip lot # from displayed list or enters lot #		
Selects puncture site		
Cleanses site with 70% alcohol and allows to dry		
Punctures fingertip with lancet		
Massages finger from palm to fingertip to obtain adequate blood sample		
Carefully touches the pink test square to the drop of blood		
Verifies proper application of blood by examining the confirmation dot; repeats application with new test strip if necessary		
Inserts test strip, blood application-side up, completely into strip holder within 2 minutes of blood application		
Records test results		
Removes test strip and discards		
Turns off glucose meter		
Disposes of sharps in needle box		

Comments

Observed By:_____ Title:_____ Date:_____

Glucose Monitoring Using SureStepPro For Adult Patients

Employee Name _____ Date _____

Circle the best answer to each question below.

1. If one of the Control Solution results falls below the expected range, you should:
   a. add or subtract the difference to or from the patient test result
   b. test the patient sample as usual
   c. add more control solution to the strip
   d. repeat the control test

2. The primary purpose of testing the High and Low Glucose Control Solutions is to:
   a. warm up the glucose meter
   b. practice using the instrument
   c. verify the proper functioning of the test system

3. If the white pad on the front of the test strip is completely saturated with blood, you have:
   a. applied too much blood
   b. applied too little blood
   c. applied an appropriate amount of blood

4. If the blue confirmation dot on the back of the test strip shows streaks or patches of white, you have:
   a. applied too much blood
   b. applied too little blood
   c. applied an appropriate amount of blood

5. After applying blood to the test strip, you have _____ minutes to insert the test strip in to the instrument:
   a. 2 minutes
   b. 30 minutes
   c. 15 minutes
   d. 5 minutes

6. If your patient is experiencing symptoms that are not consistent with the blood glucose result obtained and you have followed the test procedure, you should:
   a. repeat the patient test and then average the two results
   b. wait two hours, then repeat the patient test
   c. repeat the high and low control tests and then repeat the patient test

7. If patient results are _____ you should immediately report the result to the physician.
   a. <100 or >500 mg/dL
   b. <50 or >300 mg/dL
   c. <30 or >250 mg/dL
   d. <25 or >100 mg/dL

PERSONNEL COMPETENCY TESTING PROGRAM

CLIA'88 requires the laboratory to document the competency of all testing personnel before they begin working, every 6 months during the first year of employment and annually thereafter. The process is designed to be finished within a 30 day period from the date it is started/due. (Example: For a staff member who started on June 1, 2001, the demonstration of competency associated with the first year of employment should be finished by June 30, 2002.) An individual serving as the Director, Technical Supervisor or General Supervisor may perform this documentation. Initial demonstration of competency is handled via the Orientation checklist. Afterward, demonstration of competency is handled using the following methods and is documented on the Competency Documentation form.

1. Direct observation of specimen handling, processing and testing. While under direct observation the staff member must perform a test using the procedures described in the method manual.

2. Monitoring of results recording/reporting. The Director of the laboratory tracks corrected reports issued. The information collected on corrected reports is used by the Director to determine if an individual is appropriately recording/reporting results. Competency is considered to be demonstrated unless a staff member has a higher than average number of corrected reports. Corrective action will be taken if a staff member is repeatedly making the same error or if a staff member's error is related to gross negligence.

3. Review of QC and Maintenance records, Proficiency testing and Worksheets. The Director of the laboratory reviews all QC and Maintenance records and selected worksheets at least once a month. During this review, if substandard performance is found, it is documented and corrective action taken immediately.

4. Direct observation of the performance of maintenance and function checks. While under direct observation the staff member must perform maintenance and function checks as per the written protocol.

5. Assessment of test performance via analysis of samples with known concentrations such as previously assayed patient samples or pooled samples, Proficiency testing material or control material. Staff members are give a sample in a blinded manner for analysis. They must analyze the sample and obtain a value with a range determined by the Director of the laboratory in order to demonstrate competency.

6. Assessment of problem solving skills. This will be handled via written questions provided by the Director. The staff member being tested must provide a written response that is judged to be acceptable by the Director.

COMPETENCY DOCUMENTATION FORM

Staff Member: _____

Review type: ( ) 6 months ( ) annual Process started on: _____

SECTION 1: DIRECT OBSERVATION OF SPECIMEN HANDLING, PROCESSING AND TESTING

Briefly describe the specimen handling, processing and testing process that you observed being performed by the staff member listed above:

Signature: _____ Date: _____

SECTION 2: MONITORING OF RESULTS RECORDING/REPORTING

I certify that my monitoring of corrected reports during the last ( ) 6 months ( ) 12 months indicate that the staff member listed above has demonstrated competency in the results recording/reporting process.

Signature: _____ Date: _____

SECTION 3: REVIEW OF QC AND MAINTENANCE RECORDS, PROFICIENCY TESTING AND WORKSHEETS

I certify that my monitoring of maintenance records, proficiency testing reports and worksheets during the last ( ) 6 months ( ) 12 months indicate that the staff member listed above has demonstrated competency in this area.

Signature: _____ Date: _____

SECTION 4: DIRECT OBSERVATION OF THE PERFORMANCE OF MAINTENANCE AND FUNCTION CHECKS

Briefly describe the maintenance and function checks that you observed being performed by the staff member listed above:

Signature: _____ Date: _____

SECTION 5: DIRECT ANALYSIS OF SAMPLE

List the sample tested, test(s) performed and results obtained. The Director will fill in the acceptable range and grade the results.

SECTION 6: ASSESSMENT OF PROBLEM SOLVING SKILLS

Please write in your answer to question number _____ from the attached Competency Questions list.

Review of answer to question by Director:

Having reviewed this document, I certify that the above listed staff member has demonstrated competency as defined in CLIA'88.

Signature: _____ Date: _____

COMPETENCY TESTING PROGRAM QUESTIONS

1. What actions would take if you had a hemolyzed sample with an order for potassium?

2. What actions would you take if you received an unlabeled sample from the Outpatient lab?

3. A potassium of 6.5 meq/l is obtained on a sample from a patient located in an inpatient unit. What action would you take?

4. A glucose of 43 mg/dl is obtained on a sample from an outreach account. What action would you take?

5. The Axsym has just gone down with a bad power supply about 30 minutes ago. You receive an order for a STAT digoxin. What action would you take?

6. You are working on the LX20 and the last 5 samples with electrolytes have anion gaps <5. Is any action needed on you part? If yes, what would you do?

7. You run a blood gas sample and the pH values on the two instruments are different by 0.06. Do you report the results? If not, what action would you take?

8. You get a blood lead value on a sample of 33 ug/dl. What actions do you take?

9. You get an order for an HCG (test code 4943) on a 63 year old woman. What do you do?

10. You get a calcium value of 2.0 mg/dl. What actions do you take? What are the possible causes of the results?

11. A caller requests the sample requirements for a test you never heard of. How do you handle that call?

12. You receive an unlabeled sample on a patient that was drawn during a code. How do you handle this situation?

13. You receive a grossly lipemic sample for a cardiac risk profile. What actions do you take?

14. Before the beginning of a Glucose Tolerance, a patient as a fasting glucose of 315 mg/dl. What actions do you take?

15. At the 21/2-hour mark of a Glucose Tolerance a patient reports feeling faint. What actions do you take?

EFFECTIVE DATE

June 3, 1993

WRITTEN BY

James Dohnal, PhD

LIST OF WORKS CONSULTED

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