YALE-NEW HAVEN HOSPITAL	TITLE: **Proficiency Testing Policy**		**DEPT OF LAB MEDICINE Immunology, Flow Cytometry, and Molecular Diagnostics Laboratories**
			DOCUMENT IMM90
			Page 1 of 7
WRITTEN BY: Teodorico Lee Penny Smith Ben Davidson	**EFFECTIVE DATE:** November 13, 2001	**REVISION:** August 30, 2012	**SUPERCEDES:**

POLICY FOR TESTING OF CAP PROFICIENCY SAMPLES

Note: Testing of all CAP proficiency samples will be performed by YNHH. At no time are samples sent to reference laboratories for testing. Test results of CAP proficiency samples are not shared with any outside laboratories.

A. Processing

When CAP proficiency samples arrive in the laboratory the chief technologist, assistant chief technologist, coordinator or Technologist B will process as follows:

1. Fill out the CAP Proficiency testing form (Doc# IMM 90-A). Enter the survey name and the received date. List all samples and the tests to be performed on those samples. This form will be used as a requisition to accession the samples.

2. Accession requisitions as per established laboratory policy.
   - Last Name CAP, First name Sample # (ex CAP, M-04)
   -DOB 1/1/1901
   -Ward, type either PROFY or 00026 (courtesy)
   -Physician, type 659 (Dr. Smith)

3. Track collection labels. Place collection label on CAP form and aliquot labels on correct tube types.

4. Aliquot samples and distribute to correct racks for testing. Follow storage guidelines given in the CAP instructions that accompany the survey.

5. If survey is to be shared with another YNHH laboratory, copy the CAP documents and forward the samples to the appropriate lab.

6. Refrigerate the original bottles in a bag labeled with the CAP name and received date. After testing laboratory technologists should place the sample aliquots tested in the same bag. After results have been entered, samples are frozen at -20.

B. Testing

1. A CAP analyte is tested, by the technologist scheduled to perform the test that week. An effort will be made when possible to distribute CAP samples so that the same technologist does not perform all the proficiency samples for that test in a given year.

2. The technologist will make any necessary preparatory work rehydration, etc., as is necessary to run that analyte following CAP directions listed on the survey form.

3. The results are entered into the LIS computer by the testing technologist. Samples should be placed in the refrigerator until after results are reported.

4. After reporting, all samples are frozen at -20°C until the survey results have come back. If no investigative work needs to be done, the samples are discarded after 1 year.

C. Reporting

1. The Assistant Chief Technologist, Laboratory Manager or Coordinator will print LIS reports for all samples. These reports are used to enter results into the resulting forms located on the CAP website.

2. The information sheet (Doc# IMM 90-B) is filled out listing the survey name, date and tests, this form will serve as the attestation page. The technologist performing each test must sign this form.

3. The Laboratory Director signs the original survey signature page. In his absence the Laboratory Manager or Assistant Chief Technologist will take responsibility for signing the survey signature page(s). These names are entered electronically onto the CAP survey report sheet.

4. The survey is electronically approved on the CAP website. Before approval a copy is electronically saved.

D. Reviewing of Survey Results

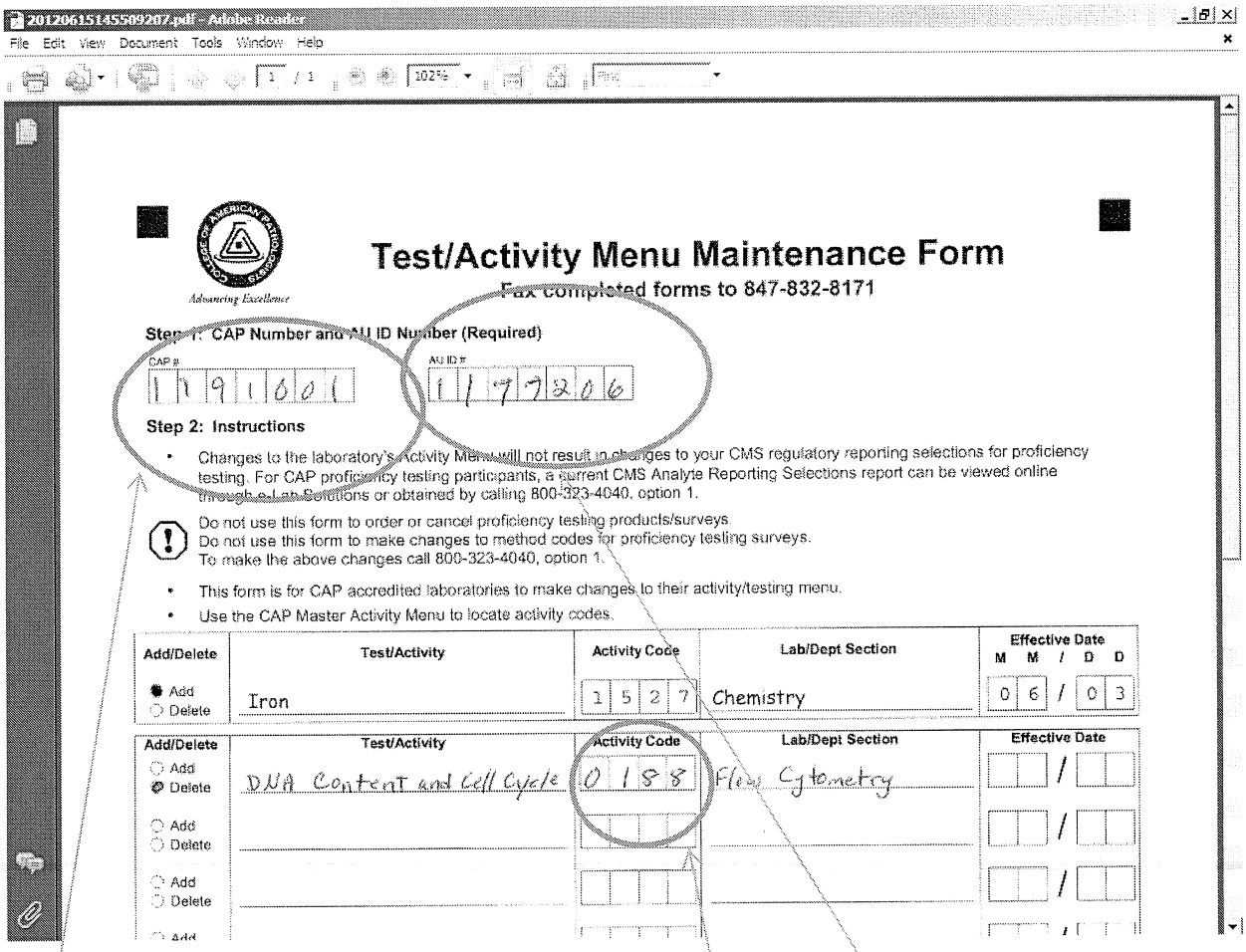
1. When the survey results come back they are given to the Department Chair who then reviews the results. If all results are acceptable, the form will be initialed and dated. This will be given to the Laboratory Manager to review and sign and then to the Assistant Chief Technologist or Coordinator. Documentation of the performing technologist is kept and is used to evaluate technical competency. A CAP Action Report (DOC# IMM 90-C) is filled out and a discussion of discrepant results is held by the Director, Manager, and Assistant Chief Technologist on all surveys. Those analytes on which there is no grade or consensus are evaluated by reviewing the Participant Summary Report. Results that are inconsistent with the majority of laboratories participating in the survey are treated as "unacceptable".

2. If there are any "unacceptable" results the Assistant Chief Technologist will use the Corrective Action Check List (Doc# IMM 90-E) to collect all information regarding that run (controls, ranges, etc.) and ask that the sample be re-tested. If needed, another sample will be purchased from CAP.

3. All results of the investigation are entered on to the CAP Action Report and are reviewed with the Laboratory Director. A copy of the report is kept in the testing Laboratory and in the office of the Compliance officer. All repeat violations that require CAP notification are forwarded to CAP by the Department of Lab Medicine's Compliance officer. The Laboratory Manager and Assistant Manager will evaluate each case to see if action is needed to prevent future errors. For example, Technologist retraining, process change, etc.

4. A signed copy of the CAP Evaluation, along with the CAP Proficiency testing form and the Information sheet are kept in the CAP binder in the Assistant Chief Technologist's office. CAP Evaluation reports and Participant summary reports are also kept electronically.

E. Adding and Deleting from CAP Activity List



Test/Activity Menu Maintenance Form

Fax completed forms to 847-832-8171

Step 1: CAP Number and AU ID Number (Required)

CAP # 7191001

AU ID # 1177206

Step 2: Instructions

- Changes to the laboratory's activity Menu will not result in changes to your CMS regulatory reporting selections for proficiency testing. For CAP proficiency testing participants, a current CMS Analyte Reporting Selections report can be viewed online through e-Lab Solutions or obtained by calling 800-323-4040, option 1.

Do not use this form to order or cancel proficiency testing products/surveys.
Do not use this form to make changes to method codes for proficiency testing surveys.
To make the above changes call 800-323-4040, option 1.

- This form is for CAP accredited laboratories to make changes to their activity/testing menu.
- Use the CAP Master Activity Menu to locate activity codes.

Add/Delete	Test/Activity	Activity Code	Lab/Dept Section	Effective Date (MM/DD)
(•) Add ( ) Delete	Iron	1527	Chemistry	06/03
( ) Add (•) Delete	DNA Content and Cell Cycle	0188	Flow Cytometry	/
( ) Add ( ) Delete				/
( ) Add ( ) Delete				/

#1. Fill out - YNHH's AU # is listed as follows: 1177206

#2 Fill out CAP # can be found listed in the CAP PT documents

#3. Fill out Add/Delete

#4 Fill out Test/Activity Name

#5 Fill out the activity Code: you can find out by looking in the CAP website (cap.org), click Lab Accreditation, lower right click Lab Activity list…select and view activity menu for main lab.

F. ANALYTES NOT COVERED BY CAP PROFICIENCY TESTING

For analytes that are not covered by CAP proficiency testing, alternate proficiency is performed at least biannually. The analytes and the method for accessing proficiency are listed below. The Medical Director reviews all results to determine acceptability.

Participation in the reagent manufactures proficiency program

CH50
A proficiency program provided by Diasorin is used. Samples are received 3 times a year and are overseen by the Assistant Chief Technologist. They are processed, tested, and reviewed the same as a CAP proficiency sample.

Free Kappa & Lambda Light Chain
Proficiency testing for these analytes is provided by the Binding Site's "Improve Quality Assurance Scheme" program. These samples, both urine (twice a year) and serum (4 times a year) are overseen by the Assistant Chief Technologist. Both serum and urine samples are assayed for IFE and kappa free and lambda free light chains. They are processed, tested and reviewed the same as a CAP proficiency sample.

Split sample analysis with reference or other laboratories

Anti Platelet Antibody, Indirect
Samples purchased from ARUP Laboratories.

DNase B
Samples sent to Quest Laboratories

Cold Agglutinins
Samples sent to ARUP Laboratories

Cryoglobulins
Samples sent to ARUP Laboratories

H.pylori IgM
Samples sent to Mayo Laboratories

ADAMTS13 Activity w/ Reflex to Inhibitor
Samples sent to Western Pennsylvania Hospital

Reticulocyte Platelet Assay
Split samples are run by two technologists.

Blinded sample analysis

Cyclin D1
Blinded patient samples are run biannually by the technologists as a means of performing quality control and proficiency testing. Blinded samples (if possible, normal, abnormal, and intermediates) should be made and kept current. When complete, results are then compared to the expected results from prior testing and must fall within 2SD.

Acute Lymphocytic Leukemia Screen
Blinded patient samples are run biannually by the technologists as a means of performing quality control and proficiency testing. Blinded samples (if possible, normal, abnormal, and intermediates) should be made and kept current. When complete, results are then compared to the expected results from prior testing and must fall within 2SD.

INV16 Quantitation
Blinded patient samples are run biannually by the technologists as a means of performing quality control and proficiency testing. Blinded samples (if possible, normal, abnormal, and intermediates) should be made and kept current. When complete, results are then compared to the expected results from prior testing and must fall within 2SD.

AML-ETO t(8,21) Quantitation
Blinded patient samples are run biannually by the technologists as a means of performing quality control and proficiency testing. Blinded samples (if possible, normal, abnormal, and intermediates) should be made and kept current. When complete, results are then compared to the expected results from prior testing and must fall within 2SD.

At the Laboratory Directors discretion an alternative reference labs can used. Also other methods which may be utilized include:

- Split samples with an established in-house method (blinded)
- Clinical validation by chart review

Non-CAP proficiency testing should be treated as closely to CAP proficiency testing as possible. All results of alternate proficiency testing are reviewed by the Medical Director for acceptability and documented in the Non-CAP Proficiency binder. Results of the survey with documentation of the Director's Review with signature are kept in this binder as well. These results are also used for assessment of technical competency.

Appendix

Document Name	Document Number	Use
CAP Proficiency testing form	Doc# IMM 90-A	Accession CAP samples
Information sheet	Doc# IMM 90-B	Special Handling form
CAP Response form	Doc# IMM 90-C	Response to incorrect CAP PT
Non-CAP Proficiency form	Doc# IMM 90-D	Log of non-CAP PT results
Corrective Action Checklist	Doc# IMM 90-E	Incorrect CAP PT documentation form
CAP Activity List	Doc# IMM 90-F	List of all CAP PT

CAP PROFICIENCY TESTING
Doc IMM 90-A

SURVEY: DATE:

CAP NUMBER: TEST:

PROCESSING:

TESTING: SEE ATTACHED INFOSHEET

REPORTING:

REVIEW:

COMMENTS:

CAP Information Form

Doc IMM 90-B

College of American Pathologists

Survey: **Rec'd:**

We the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient samples.

Cap#	Test	Tech	Results	Comments

CAP Response Form

Doc# IMM 90-C

Today's Date_____

Survey _____ Date Mailed_____

Laboratory _____ Manager/Director_____

Test_____

Comments from Brian Smith, MD:

Response:

If an action report necessary, please attach a copy of the report.

Please respond to the above comments from Dr. Smith within 4 weeks. If you are not complete with your response, let Brian know that there will be a delay. Thank you.

Send response to Rita Napierkowski
Lab Medicine
CB 407

Non-CAP Proficiency Testing Form

Document # IMM90-D

Test:

Date:

	Sample 1	Sample 2
Order #		
Source of sample		
YNHH Result		
Reference Lab/ Result		
Acceptable Yes/No		
Comments		

_____ _____

Manager/Date Director/ Date

CAP SURVEY RESULTS OUTSIDE ACCEPTABLE LIMITS
DOCUMENTATION OF CORRECTIVE ACTION
Document IMM90-E

NAME OF SURVEY	SURVEY #	REPORT DATE	EVAL DATE

RESULT(S) OUTSIDE ACCEPTABLE LIMITS

Result	Mean	S.D.I.

Check for Transcription Errors	
Check for Calculation Err	
Check for Analysis Errors	
Check QC Data	
Check Instrument Calibrat	
Rerun Specimen (if possib	
Other	

Reviewed by: _____ Date: _____

Document Authors
Teodorico Lee
Penny Smith
Ben Davidson
August 30, 2012

Signature Approval for Annual Review

Title: Proficiency Testing Policy
Document #: IMM 90

Name (Print)	Title	Signature	Date of Review	Revision Page and Section # (Use Procedure Review Log to document staff review)	Issue Date for Training if Applicable	Effective Date for Use
TEODORICO LEE	LAB MANAGER	Teodorico Lee	8/10/09	New Signature Page.	N/A	08/10/09
BRIAN SMITH	LAB DIRECTOR	Brian R. Smith MD	8/21/09	New Signature Page.	N/A	08/10/09
TEODORICO LEE	LAB MANAGER	Teodorico Lee	10/25/10		N/A	10/26/10
BRIAN SMITH	LAB DIRECTOR	Brian R. Smith MD	10/26/10		N/A	10/26/10
TEODORICO LEE	LAB MANAGER	Teodorico Lee	10/25/11	Changed name to Proficiency Testing Policy and included section on Non-CAP proficiency testing. Retired policy for Analytes Not Covered by CAP. Updated process for accessioning. Added no referral and no result sharing comment.	N/A	10/24/11
BRIAN SMITH	LAB DIRECTOR	Brian R. Smith MD	10/25/11		N/A	10/24/11
TEODORICO LEE	LAB MANAGER	Teodorico Lee	11/7/12	Consolidated Proficiency Testing Policies from Immunology, Flow Cytometry and Molecular Diagnostics. Section added on adding and deleting from the CAP activity list. Document E added to aid in investigating incorrect CAP results.	N/A	10/11/12
BRIAN SMITH	LAB DIRECTOR	BRS	10/19/12		N/A	10/11/12
JOHN G HOWE	LAB MANAGER	John G. Howe	10/12/12		N/A	10/11/12
RICHARD TORRES	LAB DIRECTOR		11/6/12		N/A	10/11/12