



VETERANS ADMINISTRATION MARYLAND HEALTH CARE SYSTEM
BALTIMORE DIVISION
10 NORTH GREENE STREET
BALTIMORE, MD 21201

GEN00005.2

PATHOLOGY & LABORATORY MEDICINE SERVICE

CAP Compliance And Proficiency Testing Challenges version 2 General Procedure # GEN00005

Principle: It is the policy of Pathology & Laboratory Medicine Service (P&LMS) to strive to meet all terms of the College of American Pathologist (CAP) regarding the accreditation of this laboratory. P&LMS will participate in proficiency testing for all analytes.

CAP Compliance

The CAP will be notified immediately for:

- a. Adverse media attention related to laboratory performance. The lab must report adverse incidents to the CAP within 2 days after learning of an investigation or adverse media attention.
- b. All change in the labs must be submitted to the CAP on a Test Menu change form and an updated master after list prior to the start of patient testing.
- c. Change in directorship, location, ownership, name, insolvency, or bankruptcy must be reported to the CAP no later than 30 days. Any unexpected changes no later than two working days. The following forms must be submitted to the CAP:
 - i. Notification of Change Form
 - ii. A photocopy of your Curriculum Vitae (CV) *without* publications
 - iii. Director CV must be signed and dated by director within the last 24 months
 - iv. CV must reflect the experience and/or training listed under Step 2: Director Qualifications
 - v. Attachment A – Laboratory Director Questionnaire
 - vi. Attachment B – Terms of Accreditation
 - vii. Include an Organizational Chart or diagram illustrating lines of authority and responsibility for laboratory operations. Include both names and titles.

If there is a change in directorship, the new director or designee will ensure that laboratory procedures are well documented and undergo at least bi-annual review.

- All supervisors will present their section's current procedure manual to the director for his/her review.
- Any changes deemed necessary by the new director or designee will be discussed with the appropriate staff.
- A "Change in Directorship" cover sheet with the directors signature and date of review will be placed in each manual.



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Receipt of Proficiency Testing (PT) Challenges:

1. Upon receipt, each section supervisor or designee will assign CAP surveys to ensure rotation amongst all techs that usually perform the patient testing for those parameters.
2. Read and follow all survey instructions. This includes test handling, reconstitution and diluent requirements, stability parameters, calculations and pretreatment requirements.
3. Verify method and instrument codes.
4. All CAP specimens will be integrated within the routine workload, and analyzed by personnel who routinely test patient samples, using the same primary method systems as for patient samples
5. Proficiency testing samples normally tested within the laboratory are not to be sent to any reference laboratory for testing or accepted from another laboratory.
6. There will be no inter-laboratory communication about the proficiency samples before results are submitted to the proficiency testing provider.

Receipt of Proficiency Testing Evaluations:

1. When the evaluation reports are received back from CAP, they will be reviewed by the Quality Management Technologist and Section Supervisor. All discrepancies will be resolved in the time frame required.
2. All unacceptable responses must be investigated and corrective actions must be documented in the Proficiency Survey Follow-up Form GEN00005A (Attachment 1). The results of this assessment must be documented in the Proficiency Survey Follow-up Form. Any corrective or preventive action documented must be first reviewed by the QM Technologist, then signed and approved by the Chief of Pathology.
3. Further investigation and documentation may be requested by the VA Regional Office (VACO) depending on the exception code or failure. A copy of the Proficiency Survey Follow-Up Form and additional documentation will be submitted to the regional office via fax or email by the QM Technologist
4. All PT challenges not graded for the following reasons:
 - a. No results submitted, Results for this kit were received past the due date or Specimen problem; must be investigated as to the reason no results were submitted. All findings will be documented on the PT Follow-up Form. Must be assessed by another method, to be determined by the section supervisor.
 - b. Lack of consensus or education challenges; the supervisor will review the CAP Participant Summary booklet supplied with each survey report to evaluate the labs results for accuracy. All findings will be documented on the CAP report on the same page as the analyte and code with date and initials of the supervisor.



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REFERENCES:

1. CAP General Checklist, Northfield IL, 2016
2. VHA HANDBOOK 1106.01, *PATHOLOGY AND LABORATORY MEDICINE SERVICE (P&LMS) PROCEDURES* January 29, 2016

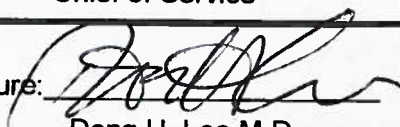
ATTACHMENTS:

1. Proficiency survey follow-up form GEN00005A
2. Delegation Form GEN00005B




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DATE ADOPTED	Author of Procedure/Policy	Chief of Service
1/16/2008	Paul D. Gruver, MT	Signature:  Dong H. Lee M.D.

Policy/Procedure(s) Retired:		Date retired:
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Review Date	Version Number	Signature of reviewer
11/13/17	2	

REVISION HISTORY

Date revised	Revision #	Changes made	Signature
9/30/17	2	Reformatted, added notification of any changes to CAP. Delegation of competency assessment. Updated information for handling of proficiency testing specimens and testing results.	

Proficiency Survey Follow-up

Laboratory: _____

Analyte: _____

Survey: _____ Kit #: _____

Non-acceptable (overall satisfactory)

Specimens: _____

Failure (overall unsuccessful)

Date: _____

Shift/Trend

Problem: _____

Assessment review:

Yes	No	N/A
Yes	No	N/A
Yes	No	N/A

1. PT survey report examined for discrepancies

2. Clerical error

3. Method history reviewed (check all that apply)

Methodology review

Quality control

Maintenance records

Lot numbers

Personnel competency

Technical review

Policy & procedure

Yes	No	N/A
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4. PT problems - last three challenges

Yes	No	N/A
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5. Manufacturer consulted

Yes	No	N/A
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6. Reassayed PT material (If no, comment on back)

Yes	No	N/A
-----	----	-----

7. Linearity study performed

Yes	No	N/A
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8. Reference method comparison

Yes	No	N/A
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9. Survey material problems investigated

Handling

Reconstitution

Storage

Analysis sequence

Matrix effects

Investigation: _____

Conclusion: _____

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Proficiency Follow-up
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Survey _____ Analyte _____

Measures taken to prevent recurrence: _____

Evidence of correction: _____

Comments: _____

Investigator signature: _____ Date: _____

Quality Management Technologist: _____ Date: _____

Additional Reviews:

Section Supervisor: _____ Date: _____

Section Chief: _____ Date: _____

Chief, Pathology & Laboratory Medicine Service Date: _____

Attach additional documentation of necessary

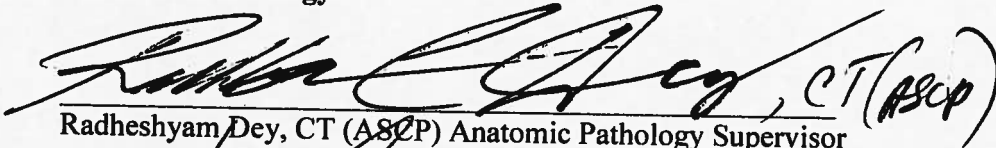
**VA Maryland Health Care System
10 North Greene Street
Baltimore, MD 21201**

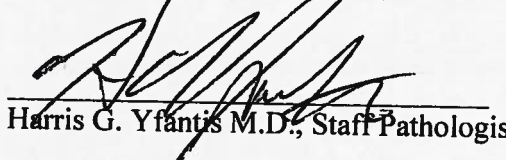
Delegation of Authority

The following persons have the authority to approve and sign the following items on my behalf:


- Competency Assessment
- Proficiency Testing (Attestation Form)

Anatomic Pathology:

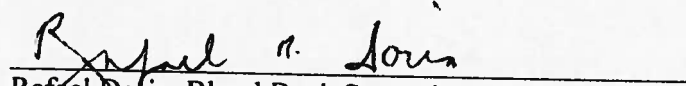

Radheshyam Dey, CT (ASCP) Anatomic Pathology Supervisor

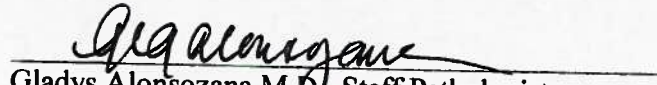

Harris G. Yfantis M.D., Staff Pathologist

Ancillary Testing:


Soudebeh H. Soleimannour, MT (ASCP), Ancillary Testing Coordinator

Blood Bank:


Rafael Dofia, Blood Bank Supervisor

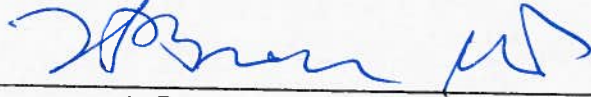

Gladys Alonsozana M.D., Staff Pathologist

Chemistry:



10.26.17

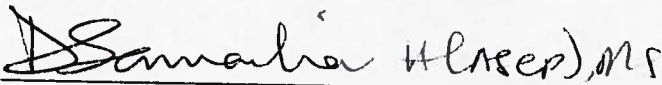
John Coulter, MT (ASCP) Chemistry Supervisor



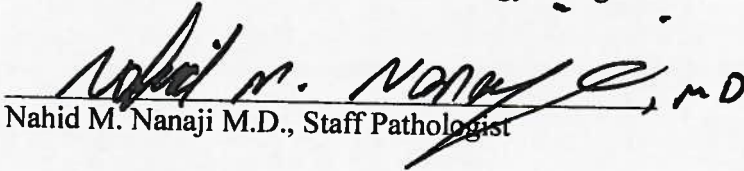
26 Oct 2017

Lawrence A. Brown M.D., Staff Pathologist

Hematology:



Daniel Samaila, MT (ASCP) Hematology, Coagulation and Urinalysis Supervisor

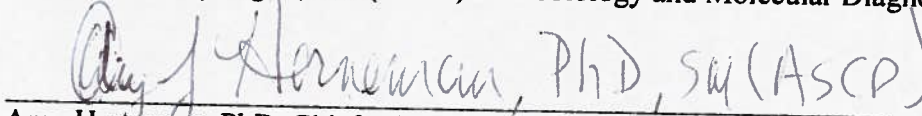


Nahid M. Nanaji M.D., Staff Pathologist

Microbiology:



Andrea Appleby-Sigler, MT (ASCP) Microbiology and Molecular Diagnostics Supervisor



Amy Hornehan, PhD. Chief Microbiology and Molecular Diagnostics

Approved by:



10/26/17

Dong H. Lee, M.D, Chief of P&LMS VAMHCS