Overview of Department Quality Control Program Administrative Procedure 117.A

PURPOSE:

To provide an overall summary of the quality control processes and programs used by the Clinical and Anatomic Pathology Laboratories.

PROCEDURE:

- A. The Quality Control Programs of the Department are the responsibility of the Division Directors (Anatomic and Clinical pathology), the Section Medical Directors (e.g. Hematology, Transfusion Services, Chemistry, Immunology and Flow Cytometry, Special Chemistry and Toxicology, Microbiology, and Molecular), the Technical Supervisors and staff. Division Directors and Section Medical Directors may delegate defined review responsibilities to technical section licensed supervisors and/or specialists.
- B. Each Division and/or Section maintains its own written quality control procedures that define the goals, procedures, policies, tolerance limits, corrective action and related information for monitoring analytic performance.
 - 1. The Quality Control records of each section will be well organized to permit regular review by the responsible technical supervisor, technical specialist and medical director.
 - 2. Quality Control records of each technical section will be retained for a minimum of three (3) years (5 years for transfusion medicine).
 - 3. Each section will establish a mechanism to verify the comparability of results for tests performed using different methodologies, instruments or for multiple test sites using the same instruments. Comparison testing will be performed at least twice annually. There must be a defined mechanism to verify comparability of patient results throughout the clinically appropriate ranges.
 - 4. Each section, when applicable, will maintain procedures to verify the precision and accuracy of patient test results when tests are performed where calibration and control materials are not available.
- C. Review and evaluation documentation of processes should be included in each technical section's quality control procedures.

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D. Review and evaluation documentation of proficiency testing may be included, but is also included in the departmental proficiency testing procedure.

REFERENCES:

- College of American Pathologists, Laboratory General and All Common Checklists; 2021 Edition.
- California Business and Professions Code- CBPC1265 J(2)
- Code of Federal Regulations(CFR), Title 42

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	Revised by		Date	by
1/99	D. O'Sullivan	New	1/99	R. Green
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12/01	D. O'Sullivan	Annual Review	12/01	R. Green
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9/03	R. Becker	Annual Review	9/03	R. Green
10/04	R. Becker	Annual Review	10/04	R. Green
10/05	R. Becker	Annual Review	10/05	R. Green
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6/17	N. Kaur	Revised: Updated Retention time	6/17	L. Howell
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PROCEDURE HISTORY

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	reference	OnBase