COLLEGE of AMERICAN PATHOLOGISTS

CAP#: 2143401
AU-ID: 1186418
January 29, 2019

Thomas S. DeNapoli, MD
Children's Hospital of San Antonio
CHofSA Laboratory
333 N Santa Rosa Street
San Antonio, Texas 78207-3108

Dear Dr. DeNapoli:

The College of American Pathologists (CAP) is pleased to advise you that the medical laboratory you direct, Children's Hospital of San Antonio CHofSA Laboratory, in San Antonio, Texas, has successfully met the Laboratory Accreditation Program Standards for Accreditation in the area(s) listed on the attached sheet. **Please retain this letter and list of accredited services in your records, as this is your official notification of accreditation.**

Your Certificate of Accreditation is enclosed. Accreditation is valid for two-years and is maintained through continuous compliance with the Terms of Accreditation contained in the attached document.

The Accreditation Committee congratulates you on the accreditation of the laboratory under your direction and the excellence of the services you are providing. Please remember CAP accreditation is not a substitute for continuous in-depth monitoring by the laboratory and its personnel to maintain a safe and properly functioning laboratory. We look forward to working with you in the future and commend your achievement of the "gold standard" of laboratory accreditation.

Sincerely,

Michael B. Datto, MD, PhD, Accreditation Committee Chair

cc: Walter H. Henricks, MD, Chair, Commission on Laboratory Accreditation

325 Waukegan Rd.
Northfield, IL 60093
cap.org

COLLEGE of AMERICAN PATHOLOGISTS

Terms of Accreditation

- A laboratory that is accredited by CAP or that has applied for accreditation must cooperate in any CAP investigation or inspection and promptly notify the CAP if the laboratory becomes:
  a. The subject of an investigation by a government entity (including federal, state, local, or foreign), or
  b. The subject of a validation inspection, or
  c. The subject of adverse media attention.
- Promptly notify the CAP if the laboratory discovers actions by laboratory personnel that appear to violate federal, state, or local laws that regulate laboratories.
- Have a written procedure for employees to communicate concerns about quality and safety to management and for management to investigate employee complaints. Incorporate corrective or preventive actions into the laboratory Quality Management Plan.
- Provide a trained inspection team comparable in size and scope to that required for its own inspection if requested by the regional and/or state commissioner at least once during the two-year accreditation period.
- Participate annually in a CAP accepted proficiency testing program, if applicable and, if subject to US CLIA regulations, meet the proficiency testing requirements in subpart H of the US CLIA regulations.
- Promptly notify the CAP and, if subject to US CLIA regulations, the Centers for Medicare and Medicaid Services (CMS), in writing 30 days prior to any changes in the following: directorship, location, ownership, name, insolvency or bankruptcy.
- Promptly notify the CAP when there is a change in the laboratory's test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing.
- Authorize the CAP to release its inspection and proficiency testing data and other information required by law to the appropriate regulatory or oversight agencies such as CMS, Department of Veterans Affairs, Department of Defense, Joint Commission, HFAP(AOA), UNOS, or state/provincial agencies.
- If the laboratory is subject to US CLIA regulations:
  - Make available on a reasonable basis the laboratory's annual PT results upon request of any person;
  - Allow CMS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operation and permit CMS to monitor the correction of any deficiencies found through such an inspection;
  - Obtain a CLIA Certificate of Accreditation and pay all applicable fees as a CLIA-certified laboratory if it will use CAP accreditation to meet CLIA certification requirements.
- Submit a completed Self-Inspection Verification Form in the interim year.
- Accept and adhere to the *Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design*, if the laboratory is/or will use the CAP Certification Mark of accreditation. The Agreement may be downloaded and printed from the CAP web site.
- Submit only documentation and other materials to CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations unless the laboratory must submit PHI to CAP in order to respond to a deficiency or patient complaint.
- Refrain from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.

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Northfield, IL 60093
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CHofSA Laboratory

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AU ID: 1186418

The above Laboratory is accredited by the College of American Pathologists Laboratory Accreditation Program for the following services:

All Common
Anatomic Pathology Processing
Autopsy Pathology
Bacteriology
Body Fluid Analysis
Chemistry
Coagulation
Cytology Processing
Cytology Screening
Director Assessment
Director/Organizational Assessment
Electron Microscopy
Flow Cytometry
Hematology
Immunohematology
Immunology
Intraoperative Consultation
Laboratory General
Molecular Microbiology
Mycobacteriology
Mycology
Non-Gynecologic Cytopathology
Parasitology
Point of Care Testing - Non-Waived
Point of Care Testing - Waived
Special Chemistry
Surgical Pathology
Toxicology
Transfusion Services
Urinalysis

This accreditation is valid for the period ending February 04, 2021.

PLEASE RETAIN THIS DOCUMENT IN YOUR RECORDS

Children's Hospital of San Antonio

CHofSA Laboratory

LAP Number:	2143401
AU ID:	1186418
Reference Number:	45D0054350

The Laboratory Accreditation Program currently has the subspecialty information listed below on file for your laboratory. This information is used for reporting to regulatory agencies.

ABO Group/Rh Type
Antibody Detection (Non-Transfusion)
Antibody Detection (Transfusion)
Antibody Identification
Bacteriology
Compatibility Testing
Cytology
Endocrinology
General Immunology
Hematology
Histopathology
Mycobacteriology
Mycology
Parasitology
Routine Chemistry
Syphilis Serology
Toxicology
Urinalysis
Virology