

ClinImmune HLA and SCL Lab - Scope of Service

Purpose

The purpose of this document is to describe the testing and client services offered by the ClinImmune HLA and SCL lab and to fulfill the requirement of College of American Pathologists Laboratory General Standard GEN.13820.

The Clinical Laboratory Services provides:

- Transplant Donor and recipient HLA typings
- Patient PRA analysis and HLA compatibility testing
- Storage, Processing, and distribution of HPC,-Apheresis, HPC-Marrow, Autologous parathyroid products to client hospital
- Quality test results in an effective time frame to support treatment -see individual JWAs for specific turnaround times
- Graduate student Education
- Clinical trial Studies Support

Laboratory Activity Menu (ClinImmune CAP# 2182821)

Histocompatibility Laboratory (Section ID: 1320512) - Activities

Type: S - Scope of Service, R - Reportable Assay

Activity Name	Discipline	Subdiscipline	Type
ABO blood grouping for transplantation	Histocompatibility Testing	HLA Serology	R
BM/stem cell transplantation, related donor	Histocompatibility Testing	Clinical Transplantation Support	S
BM/stem cell transplantation, unrelated donor	Histocompatibility Testing	Clinical Transplantation Support	S
C1q complement binding antibody, micro-bead assay	Histocompatibility Testing	HLA Solid Phase Assays	R
HLA B-Cell crossmatching, flow cytometry	Histocompatibility Testing	HLA Flow Cytometry	R
HLA B27 typing only, PCR	Histocompatibility Testing	HLA Molecular Non-NGS	R
HLA Class I antibody ID, micro-bead assay	Histocompatibility Testing	HLA Solid Phase Assays	R
HLA Class I antibody screening, micro-bead assay	Histocompatibility Testing	HLA Solid Phase Assays	R
HLA Class I typing, generic, non-sequencing	Histocompatibility Testing	HLA Molecular Non-NGS	R
HLA Class I typing, NGS	Molecular Pathology	HLA NGS	R
HLA Class II antibody ID, micro-bead assay	Histocompatibility Testing	HLA Solid Phase Assays	R
HLA Class II antibody screening, micro-bead assay	Histocompatibility Testing	HLA Solid Phase Assays	R

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Activity Name	Discipline	Subdiscipline	Type
HLA Class II typing, generic, non-sequencing	Histocompatibility Testing	HLA Molecular Non-NGS	R
HLA Class II typing, NGS	Molecular Pathology	HLA NGS	R
HLA disease association &/or drug risk, non-NGS	Histocompatibility Testing	HLA Molecular Non-NGS	R
HLA single locus typing other than B27, NGS	Molecular Pathology	HLA NGS	R
HLA single locus typing other than B27, PCR	Molecular Pathology	Inherited Genetics	R
HLA T-Cell crossmatching, flow cytometry	Histocompatibility Testing	HLA Flow Cytometry	R
Laboratory developed test (LDT), HLA Flow	Histocompatibility Testing	HLA Flow Cytometry	S
Laboratory developed test (LDT), HLA NGS	Molecular Pathology	HLA NGS	S
NGS, analytical wet bench, HLA	Molecular Pathology	HLA NGS	S
NGS, bioinformatics, HLA	Molecular Pathology	HLA NGS	S
NGS, interpretation, HLA	Molecular Pathology	HLA NGS	S
Platelet transfusion support	Histocompatibility Testing	Clinical Transplantation Support	S
Solid organ transplant, non-renal, cadaveric donor	Histocompatibility Testing	Clinical Transplantation Support	S
Solid organ transplant, non-renal, live donor	Histocompatibility Testing	Clinical Transplantation Support	S
Solid organ transplant, renal, cadaveric donor	Histocompatibility Testing	Clinical Transplantation Support	S
Solid organ transplant, renal, live donor	Histocompatibility Testing	Clinical Transplantation Support	S
Virtual HLA crossmatching	Histocompatibility Testing	HLA Serology	S

ClinImmune Stem Cell Laboratory (Section ID: 1467848) - Activities

Type: S - Scope of Service, R - Reportable Assay

Activity Name	Discipline	Subdiscipline	Type
Bone marrow processing (for transplantation)	Transfusion Medicine/Blood Bank	Cellular Therapy Services	S
Cord blood storage and issue	Transfusion Medicine/Blood Bank	Cellular Therapy Services	S
Hematocrit, non-waived	Hematology	Hematology	R
Hematopoietic progenitor cell other, processing	Transfusion Medicine/Blood Bank	Cellular Therapy Services	S

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Activity Name	Discipline	Subdiscipline	Type
Hematopoietic progenitor cell storage and issue	Transfusion Medicine/Blood Bank	Cellular Therapy Services	S
Laboratory developed test (LDT), Hematology	Hematology	Hematology	S
nRBC count, automated	Hematology	Hematology	R
Peripheral blood stem cell processing	Transfusion Medicine/Blood Bank	Cellular Therapy Services	S
Tissue storage and issue	Transfusion Medicine/Blood Bank	Tissue Storage and Issue	S
WBC count, automated	Hematology	Hematology	R

Hours of Operation

HLA Lab (DNA and Serology)	<ul style="list-style-type: none"> Monday through Friday 8:00 AM to 10:30 PM, on-call for STAT Crossmatch and PRAs
Stem Cell Lab	<ul style="list-style-type: none"> Monday through Friday: 8:00 AM to 5:00 PM After Hours, Weekends & Holidays: As needed

The Clinical Laboratory Services further:

- Maintains appropriate accreditations and registrations
- Responds to informational needs of the clients and the community
- Participates on appropriate committees to facilitate communication of service needs, appropriate utilization management, and performance improvement efforts
- Supports, conducts, and participates in clinical research appropriate to furthering knowledge of disease and treatment

Staffing/Personnel

The laboratory consists of:

- 85 full-time equivalents (FTEs)
- Staffing plans for the individual laboratory sections developed to ensure quality of laboratory testing and predictable turn-around-times
- An organizational laboratory structure that includes laboratory leadership as follows:
 - Laboratory Administrative Director
 - Medical Director
 - Quality Director
 - Quality Manager
 - Safety and Business Managers
 - Supervisors
 - Technologists

References

1. CAP, Laboratory General Checklist, current edition.