

Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 0128 Appendix to certificate No. 0128-04

Name and Address:

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The certificate attached is an integral part of the schedule and is numbered identically התעודות המצורפתות לנספח זה מהווה חלק בלתי נפרד ממנו ומספרה זהה למספר הנספח

Schedule of Accreditation

Item	Scope Type	Site	Types of Test / Properties Measured	Materials / Samples Tested	Test principle / Characteristics	Equipment used / Work station	Opinion and Interpretation	Remarks		
Group of products: Health, Medicine - Hematology			משפחת מוצרים: בריאות, רפואה - המטולוגיה							
Biological Testing, Cell Typing by FACS Analysis			בדיקות ביולוגיות, איפיון תאי דם ב-FACS							
1	A	P	Cell Markers - Diagnosis and follow up of: Acute leukemias (AML, ALL) Chronic leukemias, (CLL, CML) Lymphomas, patient's treatment follow up of leukemia, lymphoma and BMT. Identification of lymphocyte subpopulations for diagnosis and follow up of primary and secondary immunodeficiencies (including AIDS) and autoimmune diseases, CFS	Cell Markers - Diagnosis and follow up of: Acute leukemias (AML, ALL) Chronic leukemias, (CLL, CML) Lymphomas, patient's treatment follow up of leukemia, lymphoma and BMT. Identification of lymphocyte subpopulations for diagnosis and follow up of primary and secondary immunodeficiencies (including AIDS) and autoimmune diseases, CFS	Bone marrow, peripheral blood, cell suspension of solid tissues biopsies, CSF, peritoneal and pleural fluids	מח עצם, דם היקפי, תרחיף תאים של ביופסיות רקמות מוצקות, נוזל עמוד שדרה, נוזל פלאורלי ופריטונאלי.	Immunofluorescence by Flow Cytometry	Becton Dickinson FACS caliber or FACS canto	---	AML=Acute Myelocytic Leukemia, ALL = Acute Lymphocytic Leukemia, CLL = Chronic Lymphocytic Leukemia, CML = Chronic Myelocytic Leukemia, BMT= Bone Marrow Transplantation. CFS= Chronic Fatigue Synd. CSF= CerebroSpinal Fluid. FACS= Fluorescence Activated Cell Sorter

Site: P or T or M, P-Permanent, T-Temporary, M-Mobile

Type of Scopes: A- Fixed, C- Flexible scope in analytical tests : Type of matrix, analytes, experimental systems and/or analytical characteristics may be subject to changes, in accordance with the laboratory's approved and documented procedures. For details, please refer to the list of Accredited Tests, available from the laboratory upon request.

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Schedule of Accreditation

Item	Scope Type	Site	Types of Test / Properties Measured		Materials / Samples Tested	Test principle / Characteristics	Equipment used / Work station	Opinion and Interpretation	Remarks
Group of products: Health, Medicine - Immunology & Tissue Typing					משפחת מוצרים: בריאות, רפואה - אימונולוגיה וסיווג רקמות				
Biological Testing, HLA Typing and Cross Matching, Sequencing Based Molecular Assays					בדיקות ביולוגיות, סיווג והצלבה של HLA בשיטות מולקולריות מבוססות קביעת רצף				
8	A	P	DNA Extraction	הפקת DNA	Peripheral blood Bone marrow, Cord blood, Cell suspension of solid tissues, CVS, Amniotic fluid , Nails and Saliva	Extraction by magnetic beads, Manual Extraction	Maxwell 16	---	Maxwell 16 Blood Purification kit by Promega QIA amp DNA Blood mini kit by Qiagen
9	A	P	Post transplantation monitoring	Post transplantation monitoring	DNA	DNA	STR analysis	Thermocycler Sequencer	STR- Short Tandem Repeats SGM plus Kit by ABI
10	A	P	Paternity testing (court ordered)	בדיקת אבהות (צו בית משפט)	DNA	DNA	STR analysis	Thermocycler Sequencer	STR- Short Tandem Repeats SGM plus Kit by ABI

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Schedule of Accreditation

Item	Scope Type	Site	Types of Test / Properties Measured	Materials / Samples Tested	Test principle / Characteristics	Equipment used / Work station	Opinion and Interpretation	Remarks		
Group of products: Health, Medicine - Immunology & Tissue Typing			משפחת מוצרים: בריאות, רפואה - אימונולוגיה וסיווג רקמות							
Biological Testing, HLA Typing and Cross Matching ,PCR-Based Molecular Assays			בדיקות ביולוגיות, סיווג והצלבה של HLA בשיטות מולקולריות מבוססות PCR							
11	A	P	HLA typing for Organ Transplantation (Class I+II):	HLA typing for Organ Transplantation (Class I+II):	DNA	DNA	DNA typing (Class I + ClassII), low and high resolution SSP + SSOP	Thermocycler , Luminex	---	SSP = Sequence Specific Primers SSOP = Sequence Specific Oligo Probes 1 lambda SSP kits, Unitray Kit by Lifetechnologies, Olerup ssp Kit , SSO Kit by Immucor (Lifecodes)
12	A	P	HLA Typing for Haematopoietic Stem Cell Transplantation(Class I+II): Recipient, donor- related potential donors, unrelated donor (donor registry),	HLA Typing for Haematopoietic Stem Cell Transplantation(Class I+II): Recipient, donor- related potential donors, unrelated donor (donor registry),	DNA	DNA	DNA typing (Class I + ClassII) , low and high resolution. SSP + SSOP	Thermocycler , Luminex	---	1 lambda SSP kits, Unitray Kit by Lifetechnologies, Olerup ssp Kit, SSO Kit by Immucor (Lifecodes)
13	A	P	Class I and/or II HLA typing: Support for Disease Diagnosis, Drug allergy, Disease prognosis,	Class I and/or II HLA typing: Support for Disease Diagnosis, Drug allergy, Disease prognosis,	DNA	DNA	DNA typing (Class I + ClassII) , low and high resolution SSP + SSOP	Thermocycler , Luminex	---	1 lambda SSP kits, Unitray Kit by Lifetechnologies, Olerup ssp Kit, SSO Kit by Immucor (Lifecodes)
14	A	P	HLA typing for Paternity testing (court ordered)	HLA typing for Paternity testing (court ordered)	DNA	DNA	DNA typing classI+II, low resolution (high resolution if needed), SSP + SSOP	Thermocycler , Luminex	---	1 lambda SSP kits, Unitray Kit by Lifetechnologies, Olerup ssp Kit, SSO Kit by Immucor (Lifecodes)

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Schedule of Accreditation

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Group of products: Health, Medicine - Immunology & Tissue Typing					משפחת מוצרים: בריאות, רפואה - אימונולוגיה וסיווג רקמות				
Biological Testing, HLA typing and cross matching by FACS					בדיקות ביולוגיות, סיווג והצלבה של HLA ב-FACS				
15	A	P	Cross Match for Organ Transplantation	Cross Match for Organ Transplantation	Serum, Lymphocytes	סרום, לימפוציטים	Flow XM	Becton Dickinson FACS calibur Becton Dickinson FACS canto	Flow XM- Flow Cytometry Crossmatch

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Schedule of Accreditation

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Biological Testing, Autoimmune Disease, Manual Immunoassays					בדיקות ביולוגיות, מחלות אוטואימוניות בשיטות אימונוכימיות ידניות				
16	A	P	Anti Epithelial Ab	Anti Epithelial Ab	Serum	סרום IFA	Fluorescent Microscope	---	IFA= Indirect Immunofluorescence Kit by INOVA
17	A	P	ANA (Anti –Nuclear Ab)	ANA (Anti –Nuclear Ab)	Serum	סרום IFA	Fluorescent Microscope	---	Kit by ALPHADIA
18	A	P	APCA (Anti parietal Cell Ab)	APCA (Anti parietal Cell Ab)	Serum	סרום IFA	Fluorescent Microscope	---	AMA, ASMA, APCA, are done on the same slide Kit by Kallestad
19	A	P	AMA (Anti Mitochondrial Ab)	AMA (Anti Mitochondrial Ab)	Serum	סרום IFA	Fluorescent Microscope	---	AMA,ASMA,APCA, are done on the same slide Kit by Kallestad
20	A	P	ASMA (Anti Smooth Muscle Ab)	ASMA (Anti Smooth Muscle Ab)	Serum	סרום IFA	Fluorescent Microscope	---	AMA, ASMA, APCA, are done on the same slide Kit by Kallestad
21	A	P	EMA (Anti Endomysial Ab)	EMA (Anti Endomysial Ab)	Serum	סרום IFA	Fluorescent Microscope	---	Slide by INOVA
22	A	P	GBM (Anti Glomerular Basement Membrane Ab)	GBM (Anti Glomerular Basement Membrane Ab)	Serum	סרום IFA	Fluorescent Microscope	--	Slide by INOVA
23	A	P	ANCA (Anti-Neutrophil Cytoplasmic Ab)	ANCA (Anti-Neutrophil Cytoplasmic Ab)	Serum	סרום IFA	Fluorescent Microscope	--	Screening for p-ANCA or c-ANCA Kit by INOVA
24	A	P	MPO (Anti Myeloperoxidase Ab)	MPO (Anti Myeloperoxidase Ab)	Serum	סרום ELISA	Elisa Reader	--	Ab=Antibodies ELISA=Enzyme - Linked Immuno Sorbent Assay Kit by INOVA
25	A	P	PR-3 (Anti Serine Protease 3 Ab)	PR-3 (Anti Serine Protease 3 Ab)	Serum	סרום ELISA	Elisa Reader	--	Kit by INOVA

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Biological Testing, Autoimmune Disease, Manual Immunoassays					בדיקות ביולוגיות, מחלות אוטואימוניות בשיטות אימונוכימיות ידניות				
26	A	P	ASCA (Anti Saccharomyces Cerevisiae Ab)	ASCA (Anti Saccharomyces Cerevisiae Ab)	Serum	סרום ELISA	Elisa Reader		Kit by INOVA
27	A	P	Anti RNP/SM Ab	Anti RNP/SM Ab	Serum	סרום ELISA	Elisa Reader		Kit by INOVA
28	A	P	Anti SM Ab	Anti SM Ab	Serum	סרום ELISA	Elisa Reader		Kit by INOVA
29	A	P	Anti SS-A Ab	Anti SS-A Ab	Serum	סרום ELISA	Elisa Reader	---	Kit by INOVA
30	A	P	Anti SS-B Ab	Anti SS-B Ab	Serum	סרום ELISA	Elisa Reader	---	Kit by INOVA
31	A	P	SCL-70 (Anti scleroderma 70)	SCL-70 (Anti scleroderma 70)	Serum	סרום ELISA	Elisa Reader	---	Kit by INOVA
32	A	P	tTG (Anti Tissue Transglutaminase Ab)	tTG (Anti Tissue Transglutaminase Ab)	Serum	סרום ELISA	Elisa Reader	---	Kit by INOVA

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