



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117
Testing Laboratory ISO/IEC 17025

Appendix to Certificate No. 117-04

Schedule of Accreditation

Name and Address:

Organization name Hadassah Medical Organization
Address Ein-Karem hospital
P.O.Box 12000, Jerusalem 91120 Israel
Phone +972-2-677-8191
Fax +972-2-677-6799
E-Mail (contact person) radler@hadassah.org.il
Web Site www.hadassah.org.il

This appendix includes 09 parts, one for each accredited laboratory in the list below:

| Num. | Laboratory | Phone No. |
|------|---|-----------------|
| 1. | Blood Bank (Ein-Karem) | +972-2-677-6047 |
| 2. | Blood Bank (Mt Scopus) | +972-2-584-4777 |
| 3. | Clinical Virology | +972-2-677-8570 |
| 4. | Department of Clinical Biochemistry (Ein-Karem) | +972-2-677-6551 |
| 5. | Department of Clinical Biochemistry (Mt Scopus) | +972-2-584-4771 |
| 6. | In Vitro Fertilization (IVF) (Ein-Karem) | +972-2-677-7619 |
| 7. | In Vitro Fertilization (IVF) (Mt Scopus) | +972-2-584-4643 |
| 8. | Liver Unit | +972-2-677-6894 |
| 9. | Tissue typing and Immunogenetics | +972-2-677-7801 |



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

Schedule of Accreditation

Name and Address:

Organization name Hadassah Medical Organization
Laboratory name Blood Bank
Sub division Ein-Karem hospital
Address P.O.Box 12000, Jerusalem 91120 Israel
Phone +972-2-677-6047
Fax +972-2-677-6799
E-Mail orlyz@hadassah.org.il

| 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 - Blood Bank | | | | | משפחת מוצרים: בריאות, רפואה - בנק דם | | | | | |
| Biological Testing, Identification and Characterization of Pathogenic Infections, Non-culture Identification Methods - by Autoanalysers/Manual | | | | | בדיקות ביולוגיות, זיהוי ואפיון ללא תרבית באוטואנלייזרים/ידניות | | | | | |
| 1 | A | P | HTLV I / HTLV II antibody detection | HTLV I / HTLV II antibody detection | Serum, Plasma | סרום, פלסמה | CMIA | ARCHITECT | --- | CMIA= Chemiluminescent microparticals immunoassay |
| 2 | A | P | HCV antibody detection | HCV antibody detection | Serum, Plasma | סרום, פלסמה | CMIA | ARCHITECT | --- | |
| 3 | A | P | HBsAg qualitative detection | HBsAg qualitative detection | Serum, Plasma | סרום, פלסמה | CMIA | ARCHITECT | --- | |
| 4 | A | P | <i>Treponema Pallidum</i> antibody detection | <i>Treponema Pallidum</i> antibody detection | Serum, Plasma | סרום, פלסמה | CMIA | ARCHITECT | --- | |
| 5 | A | P | HIV Ag/Ab "combo" detection | גילוי משולב של נוגדנים ואנטיגנים ל- HIV | Serum, Plasma | סרום, פלסמה | CMIA | ARCHITECT | --- | |

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

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| 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 - Blood Bank | | | | משפחת מוצרים: בריאות, רפואה - בנק דם | | | | | |
| Biological Testing, Immunoassays Autoanalysers / Manual | | | | בדיקות ביולוגיות, שיטות אימונוכימיות באוטואנלייזרים/ידניות | | | | | |
| 6 | A | P | Antibody screening | סקר נוגדנים | Whole blood | דם מלא | Glass beads agglutination | Auto-Vue INNOVA | --- |
| 7 | A | P | Blood type: A, B, O, AB, Rh, weak D | קביעת סוג דם: O, B, A, חלש D, Rh, AB | Whole blood | דם מלא | Glass beads agglutination | Auto-Vue INNOVA | --- |
| 8 | A | P | Antibody screening | סקר נוגדנים | Whole blood | דם מלא | DiaMed gel agglutination | WaDiana | --- |
| 9 | A | P | Blood type: A, B, O, AB, Rh, weak D | קביעת סוג דם: O, B, A, חלש D, Rh, AB | Whole blood | דם מלא | DiaMed gel agglutination | WaDiana | --- |
| 10 | A | P | Antibody screening | סקר נוגדנים | Whole blood | דם מלא | DiaMed gel agglutination | N.A | --- |
| 11 | A | P | Compatibility test | מבחן התאמה | Whole blood | דם מלא | DiaMed gel Indirect Anti-globulin test (IAT) | N.A | --- |
| 12 | A | P | Direct Antiglobulin Test | מבחן אנטיגלובולין ישיר | Whole blood | דם מלא | DiaMed gel agglutination | N.A | --- |
| 13 | A | P | Antibody screening | סקר נוגדנים | Whole blood | דם מלא | Tube agglutination | N.A | --- |
| 14 | A | P | Blood type: A, B, O, AB, Rh, weak D | קביעת סוג דם: O, B, A, חלש D, Rh, AB | Whole blood | דם מלא | Tube agglutination | N.A | --- |
| 15 | A | P | Compatibility test | מבחן התאמה | Whole blood | דם מלא | Tube Immediate Spin (IS) & Indirect Anti-globulin test (IAT) | N.A | --- |
| 16 | A | P | Direct Antiglobulin Test | מבחן אנטיגלובולין ישיר | Whole blood | דם מלא | Tube agglutination | N.A | --- |

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Appendix to Certificate No. 117-04

Schedule of Accreditation

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|--|------------|------|--|---|----------------------------------|-------------------------------|----------------------------|---------|-----|
| Group of products: Health, Medicine - Blood Bank | | | | משפחת מוצרים: בריאות, רפואה - בנק דם | | | | | |
| Biological Testing, Immunoassays Autoanalysers / Manual | | | | בדיקות ביולוגיות, שיטות אימונוכימיות באוטואנלייזרים/ידניות | | | | | |
| 17 | A | P | Phenotyping of red blood cells | קביעת פנוטיפ אנטיגני של התאים האדומים | Whole blood | דם מלא | Tube agglutination | N.A | --- |
| 18 | A | P | Serologic confirmation of ABO/Rh | אימות סרולוגי של סוג דם ABO/Rh | Whole blood | דם מלא | Tube agglutination | N.A | --- |
| 19 | A | P | Blood type: A, B, O, AB, Rh, weak D | קביעת סוג דם: A, B, O, Rh, AB חלש D | Whole blood | דם מלא | Agglutination | N.A | --- |
| 20 | A | P | Antibody screening | סקר נוגדנים | Whole blood | דם מלא | Agglutination | N.A | --- |
| 21 | A | P | Cold-Reactive Autoantibodies Screening | סקר נוגדנים לגילוי נוגדני קור | Whole blood | דם מלא | Tube Agglutination | N.A | --- |
| 22 | A | P | Cold-Reactive Autoantibodies Screening | Cold-Reactive Autoantibodies Screening | Whole blood | דם מלא | DiaMed gel Agglutination | N.A | --- |
| 23 | A | P | Rapid Acid Eluting of Antibodies | Rapid Acid Eluting of Antibodies | Whole blood | דם מלא | DiaMed gel Agglutination | N.A | --- |

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| Group of products: Health, Medicine - Blood Bank | | | | משפחת מוצרים: בריאות, רפואה - בנק דם | | | | | |
| Blood component preparation | | | | הכנת מרכיבי דם | | | | | |
| 24 | A | P | Blood components preparation for release on demand | הכנה ושחרור מרכיבי דם לעירוי לפי דרישה | Blood Components | רכיבי דם | N.A | HMOs blood bank software | --- |
| 25 | A | P | Blood components processing procedures | הכנת מרכיבי דם | Whole blood & Blood Components | דם מלא & רכיבי דם | Whole blood gravity Separation and filtration | N.A | --- |

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



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|---|------------|------|---|---|----------------------------------|-------------------------------|-----------------------------|--------------|-----|--------------------|
| Group of products: Health, Medicine - Blood Bank | | | | משפחת מוצרים: בריאות, רפואה - בנק דם | | | | | | |
| Whole Blood Donation/ Apheresis | | | | תרומת דם מלא / אפרזיס | | | | | | |
| 26 | A | P | Donor acceptance for Apheresis procedure | קבלת תורם לאפרזיס | --- | Donor interview | Donor History Questionnaire | --- | | |
| 27 | A | P | Donor acceptance for Whole Blood collection | קבלת תורם לתרומת דם | --- | Donor interview | Donor History Questionnaire | --- | | |
| 28 | A | P | Whole Blood collection | איסוף (תרומת) דם מלא | Whole blood | דם מלא | N.A | N.A | --- | N.A=Not Applicable |
| 29 | A | P | Hemoglobin count | ספירת המוגלובין | Whole blood | דם מלא | Optical-electronic method | HemoCue | --- | |
| 30 | A | P | Single Donor Platelets (SDP) collection | איסוף (תרומת) טסיות | Whole blood | דם מלא | Apheresis | MCS+ & TRIMA | --- | |
| 31 | A | P | Platelet count | ספירת טסיות | Single Donor Platelets (SDP) | תורם טסיות יחיד | Optical-electronic method | Sysmex | --- | |
| 32 | A | P | Whole Blood count | ספירת דם מלא | Whole blood | דם מלא | Optical-electronic method | Sysmex | --- | |
| 33 | A | P | ABO – type in plasma | קביעת סוג דם בפלסמה | Single Donor Platelets (SDP) | תורם טסיות יחיד | Tube agglutination | N.A | --- | |

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Name and Address:

Organization name Hadassah Medical Organization
Laboratory name Blood Bank
Sub division Mt. Scopus hospital
Address P.O.Box 24035, Jerusalem 91240 Israel
Phone +972-2-677-6047
Fax +972-2-677-6799
E-Mail orlyz@hadassah.org.il

| 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 - Blood Bank | | | | משפחת מוצרים: בריאות, רפואה - בנק דם | | | | |
| Biological Testing, Immunoassays Autoanalysers / Manual | | | | בדיקות ביולוגיות, שיטות אימונוכימיות באוטואנלייזרים/ידניות | | | | |
| 34 | A | P | Blood type: A, B, O, AB, Rh, weak D | קביעת סוג דם: O, B, A, חלש D, Rh, AB | דם מלא | DiaMed gel agglutination | WaDiana | --- |
| 35 | A | P | Antibody screening | סקר נוגדנים | דם מלא | DiaMed gel agglutination | WaDiana | --- |
| 36 | A | P | Antibody screening | סקר נוגדנים | דם מלא | DiaMed gel agglutination | N.A | --- |
| 37 | A | P | Compatibility test | מבחן התאמה | דם מלא | DiaMed gel Indirect Anti-globulin test) IAT | N.A | --- |
| 38 | A | P | Antibody screening | סקר נוגדנים | דם מלא | Tube agglutination | N.A | --- |
| 39 | A | P | Blood type: A, B, O, AB, Rh, weak D | קביעת סוג דם: O, B, A, חלש D, Rh, AB | דם מלא | Tube agglutination | N.A | --- |

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|--|------------|------|-------------------------------------|---|----------------------------------|--|----------------------------|---------|
| Group of products: Health, Medicine - Blood Bank | | | | משפחת מוצרים: בריאות, רפואה - בנק דם | | | | |
| Biological Testing, Immunoassays Autoanalysers / Manual | | | | בדיקות ביולוגיות, שיטות אימונוכימיות באוטואנלייזרים/ידניות | | | | |
| 40 | A | P | Compatibility test | מבחן התאמה Whole blood | דם מלא | Tube Immediate Spin (IS) & Indirect Anti-globulin test (IAT) | N.A | --- |
| 41 | A | P | Serologic confirmation of ABO/Rh | אימות סרולוגי של סוג דם ABO/Rh Whole blood | דם מלא | Tube agglutination | N.A | --- |

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Date of issue 12.06.2013 Version No. 2

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The certificate attached is an integral part of the schedule and is numbered identically התעודה המצורפת לספח זה מהווה חלק בלתי נפרד ממנו ומספרה זהה למספר הנספח



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|---|------------|------|--|---|----------------------------------|-------------------------------|----------------------------|--------------------------|-----|
| Group of products: Health, Medicine - Blood Bank | | | | משפחת מוצרים: בריאות, רפואה - בנק דם | | | | | |
| Blood component preparation | | | | הכנת רכיבי דם | | | | | |
| 42 | A | P | Blood components preparation for release on demand | הכנה ושחרור מרכיבי דם לעירוי לפי דרישה | Blood Components | רכיבי דם | N.A | HMOs blood bank software | --- |

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Schedule of Accreditation

Name and Address:

Organization name Hadassah Medical Organization
Laboratory name Clinical Virology
Sub division Ein-Karem hospital
Address P.O.Box 12000, Jerusalem 91120 Israel
Phone +972-2-677-8570; 677-7890; 677-7820
Fax +972-2-6427921
E-Mail wolfd@md.huji.ac.il
mnurit@hadassah.org.il

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|--|------------|------|-------------------------------------|----------------------------|---|---|---|---------------------------|---|
| Group of products: Health, Medicine - Microbiology, Viruses | | | | | משפחת מוצרים: בריאות, רפואה - מיקרוביולוגיה, נגיפים | | | | |
| Biological Testing, Identification & Typing Molecular Methods PCR-Based Testing | | | | | בדיקות ביולוגיות, זיהוי ואפיון בשיטות מולקולריות מבוססות PCR | | | | |
| 43 | A | P | DNA extraction | הפקת DNA | Whole blood, plasma, serum, BAL, amniotic fluid, CSF, Bone marrow, Urine, body fluids | דם מלא, פלסמה, סרום, שטיפה ברונכואלואולרית, מי שפיר, נוזל עמוד שידרה מח עצם, שתן, נוזלי גוף | MagNA PureLC total nucleic acid isolation kit (Roche) | MagNA Pure LC (Roche) | CSF= Cerebrospinal Fluid נוהל מקומי # 210.2002 |
| 44 | A | P | DNA extraction | הפקת DNA | Whole blood, plasma, serum, BAL, amniotic fluid, CSF, Bone marrow, body fluids | דם מלא, פלסמה, סרום, שטיפה ברונכואלואולרית, מי שפיר, נוזל עמוד שידרה מח עצם, נוזלי גוף | QIAamp DNA blood Minikit | QIAamp DNA Blood Mini Kit | נוהל מקומי # 210.2002 |

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| Group of products: Health, Medicine - Microbiology, Viruses | | | | | משפחת מוצרים: בריאות, רפואה - מיקרוביולוגיה, נגיפים | | | | | |
| Biological Testing, Identification & Typing Molecular Methods PCR-Based Testing | | | | | בדיקות ביולוגיות, זיהוי ואפיון בשיטות מולקולריות מבוססות PCR | | | | | |
| 45 | A | P | DNA extraction | הפקת DNA | Biopsy specimens | דגימות ביופסיה | QIAamp DNA Minikit | QIAamp DNA Mini Kit | --- | נוהל מקומי # 210.2002 |
| 46 | A | P | DNA extraction | הפקת DNA | Urine | שתן | QIAamp Viral RNA Minikit | QIAamp Viral RNA Mini Kit | --- | נוהל מקומי # 210.2002 |
| 47 | A | P | CMV (Cytomegalovirus) DNA detection by Real Time PCR (Quantitative & Qualitative) | גילוי DNA של CMV (Cytomegalovirus) בשיטת Real Time PCR (כמותית ואיכותית) | Whole blood, plasma, serum, BAL, amniotic fluid, CSF, Bone marrow, body fluids, Urine, biopsy specimens | דם מלא, פלסמה, סרום, שטיפה ברונכואלואולרית, מי שפיר, נוזל עמוד שידרה מח עצם, שתן, נוזלי גוף, שתן, דגימות ביופסיה | Real Time PCR | TaqMan (ABI PRISM) 7900HT | --- | PCR= Polymerase Chain Reaction נוהל מקומי # 210.2007 |

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| Biological Testing, Non Culture Identification Typing - Immunoassays in Autoanalysers | | | | בדיקות ביולוגיות, זיהוי ואפיון ללא תרבית - שיטות אימונוכימיות באוטואנלייזרים | | | | |
| 48 | A | P | CMV (Cytomegalovirus) IgG antibody detection | CMV (Cytomegalovirus) גילוי נוגדני IgG Serum | סרום | ELISA | VIDAS DASA 2047 | IgG=Immunoglobulin G # 210.2004 נוהל מקומי |

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Laboratory name Department of Clinical Biochemistry
Sub division Ein-Karem hospital
Address P.O.Box 12000, Jerusalem 91120 Israel
Phone +972-2-677-6551
Fax +972-2-677-6270
E-Mail awadsror@hadassah.org.il
ramia@hadassah.org.il

| 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 - Chemistry, General Biochemistry | | | | | משפחת מוצרים: בריאות, רפואה - כימיה, ביוכימיה כללית | | | | |
| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 49 | A | P | Albumin (Alb) | אלבומין Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 50 | A | P | Alk.P (Alkaline phosphatase) | Alk.P (Alkaline phosphatase) Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 51 | A | P | Direct Bilirubin D (BIL) | Direct Bilirubin D (BIL) Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 52 | A | P | Bilirubin Total (T.BIL) | Bilirubin Total (T.BIL) Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 53 | A | P | Calcium (CA) | סידן Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |

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

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Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Chemistry, General Biochemistry | | | | | משפחת מוצרים: בריאות, רפואה - כימיה, ביוכימיה כללית | | | | |
| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 54 | A | P | Calcium Urine (CAU) | סידן בשתן Urine | Chemistry analyser | COBAS 6000 | --- | | |
| 55 | A | P | Chloride (CL) | Chloride (CL) Serum | Chemistry analyser | COBAS 6000 | --- | | |
| 56 | A | P | Cholesterol (CHOL) | כולסטרול Serum | Chemistry analyser | COBAS 6000 | --- | | |
| 57 | A | P | Creatine phospho Kinase (CPK) | Creatine phospho Kinase (CPK) Serum | Chemistry analyser | COBAS 6000 | --- | | |
| 58 | A | P | Creatinine (CRE) | Creatinine (CRE) Serum | Chemistry analyser | COBAS 6000 | --- | | |
| 59 | A | P | Alanine aminotransferase (ALT) | Alanine aminotransferase (ALT) Serum | Chemistry analyser | COBAS 6000 | --- | | |
| 60 | A | P | Ammonia (AMON) | אמוניה Serum | Chemistry analyser | COBAS 6000 | --- | | |
| 61 | A | P | Aspartate aminotransferase (AST) | Aspartate aminotransferase (AST) Serum | Chemistry analyser | COBAS 6000 | --- | | |
| 62 | A | P | Diastase – Amylase (DIA) | Diastase – Amylase (DIA) Serum | Chemistry analyser | COBAS 6000 | --- | | |
| 63 | A | P | Gamma Glutamyl Transpeptidase (GGTP) | Gamma Glutamyl Transpeptidase (GGTP) Serum | Chemistry analyser | COBAS 6000 | --- | | |

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Appendix to Certificate No. 117-04

Schedule of Accreditation

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| Group of products: Health, Medicine - Chemistry, General Biochemistry | | | | | משפחת מוצרים: בריאות, רפואה - כימיה, ביוכימיה כללית | | | | |
| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 64 | A | P | Glucose (GLU) | גלוקוז Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 65 | A | P | Glucose Urine (GLUU) | גלוקוז בשתן Urine | שתן | Chemistry analyser COBAS 6000 | --- | | |
| 66 | A | P | Glucose (GLU) | גלוקוז CSF (Cerebro Spinal Fluid) | נוזל עמוד שידרה | Chemistry analyser COBAS 6000 | --- | | |
| 67 | A | P | Glucose Tolerance Test (GLU.TT) | מבחן העמסת סוכר Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 68 | A | P | Lactic Acid (LAC.AC) | חומצה לקטית Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 69 | A | P | Lactic Acid (LAC.AC) | חומצה לקטית CSF (Cerebro Spinal Fluid) | נוזל עמוד שידרה | Chemistry analyser COBAS 6000 | --- | | |
| 70 | A | P | Lactate Dehydrogenase (LDH) | Lactate Dehydrogenase (LDH) Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 71 | A | P | Lithium (LI) | ליטיום Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 72 | A | P | Magnesium (MG) | מגנזיום Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |
| 73 | A | P | Magnesium Urine (MGU) | מגנזיום בשתן Urine | שתן | Chemistry analyser COBAS 6000 | --- | | |
| 74 | A | P | Phosphate (P) | זרחן Serum | סרום | Chemistry analyser COBAS 6000 | --- | | |

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Schedule of Accreditation

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| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 75 | A | P | Phosphate in Urine (PU) | זרחן בשתן | Urine | שתן | Chemistry analyser | COBAS 6000 | --- |
| 76 | A | P | Potassium/Sodium (NA/K) | אשלגן/נתרן | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 77 | A | P | Protein Total (TP) | כלל חלבון | CSF (Cerebro Spinal Fluid) | נוזל עמוד שידרה | Chemistry analyser | COBAS 6000 | --- |
| 78 | A | P | Protein Total (TP) | כלל חלבון | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 79 | A | P | Urine Protein (UPRO) | חלבון בשתן | Urine | שתן | Chemistry analyser | COBAS 6000 | --- |
| 80 | A | P | Potassium /Sodium Urine (NAU/ KU) | אשלגן/נתרן בשתן | Urine | שתן | Chemistry analyser | COBAS 6000 | --- |
| 81 | A | P | Triglycerides (TG) | טריגליצרידים | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 82 | A | P | Urea | אוראה | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 83 | A | P | Urea Urine (UREAU) | אוראה בשתן | Urine | שתן | Chemistry analyser | COBAS 6000 | --- |
| 84 | A | P | Uric Acid (UR.AC) | חומצת שתן | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 85 | A | P | Uric Acid Urine (UR.ACU) | חומצת שתן בשתן | Urine | שתן | Chemistry analyser | COBAS 6000 | --- |
| 86 | A | P | (UA.CL) Uric Acid Clearance | פינוי חומצת שתן | Serum + Urine | סרום + שתן | Calculation | Computer Calculation | --- |

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Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Chemistry, General Biochemistry | | | | משפחת מוצרים: בריאות, רפואה - כימיה, ביוכימיה כללית | | | | | |
| Chemical Testing, Autoanalysers | | | | בדיקות כימיות, שיטות באוטואנליזרים | | | | | |
| 87 | A | P | Iron | ברזל Serum | סרום Immunochemistry | COBAS 6000 | --- | | |
| 88 | A | P | TIBC (Total Iron Binding Capacity) | כושר קשירה של ברזל Plasma | פלסמה Calculation | COBAS 6000 | --- | | |
| 89 | A | P | Albumin in Urine (ALBU) | אלבוּמין בשתן Urine | שתן Immunoturbidimetric | COBAS 6000 | --- | | |
| 90 | A | P | C-Reactive Protein (CRP) | C-Reactive Protein (CRP) Serum | סרום Immunoturbidimetric | COBAS 6000 | --- | | |

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The certificate attached is an integral part of the schedule and is numbered identically התעודה המצורפת לספח זה מהווה חלק בלתי נפרד ממנו ומספרה זהה למספר הספח



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Chemistry, General Biochemistry, Hemodynamics and Oxymetry | | | | | משפחת מוצרים: בריאות, רפואה - כימיה, ביוכימיה כללית, המודינמיקה ואוקסימטריה | | | | | |
| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | | |
| 91 | A | P | pH | pH | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- | |
| 92 | A | P | Oxygen (PO ₂) | חמצן | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- | |
| 93 | A | P | Carbon dioxide (pCO ₂) | פחמן דו חמצני | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- | |
| 94 | A | P | Carbon oxide (CO) | פחמן חד חמצני | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- | |

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Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Endocrinology | | | משפחת מוצרים: בריאות, רפואה - אנדוקרינולוגיה | | | | | | |
| Biological Testing, Immunoassays by Autoanalysers | | | בדיקות ביולוגיות, שיטות אימונוכימיות באוטואנלייזרים | | | | | | |
| 95 | A | P | β-human Chorionic Gonadotropin (β-hCG) | β-human Chorionic Gonadotropin (β-hCG) | Serum | סרום | Automated Immunoassays | COBAS 6000 | --- |

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Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

Schedule of Accreditation

Name and Address:

Organization name Hadassah Medical Organization
Laboratory name Department of Clinical Biochemistry
Sub division Mt Scopus Hospital
Address P.O.Box 24035, Jerusalem 91240 Israel
Phone +972-2-584-4781
Fax +972-2-532-3183
E-Mail barghouti@hadassah.org.il

| 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 - Chemistry, General Biochemistry | | | | | משפחת מוצרים: בריאות, רפואה - כימיה, ביוכימיה כללית | | | | |
| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 96 | A | P | Albumin (ALB) | אלבוּמין | Serum | סרוּם | Chemistry analyser COBAS 6000 | --- | |
| 97 | A | P | Alkaline phosphatase (ALK.P) | Alkaline phosphatase (ALK.P) | Serum | סרוּם | Chemistry analyser COBAS 6000 | --- | |
| 98 | A | P | Alanine aminotransferase (ALT) | Alanine aminotransferase (ALT) | Serum | סרוּם | Chemistry analyser COBAS 6000 | --- | |
| 99 | A | P | Ammonia (AMON) | אמוניה | Serum | סרוּם | Chemistry analyser COBAS 6000 | --- | |
| 100 | A | P | Aspartate aminotransferase (AST) | Aspartate aminotransferase (AST) | Serum | סרוּם | Chemistry analyser COBAS 6000 | --- | |

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Appendix to Certificate No. 117-04

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 |
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| Chemical Testing, Autoanalysers | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | | |
| 101 | A | P | Calcium (CA) | סידן Serum | סרום | Chemistry analyser COBAS 6000 | --- | |
| 102 | A | P | Calcium Urine (CAU) | סידן בשתן Urine | שתן | Chemistry analyser COBAS 6000 | --- | |
| 103 | A | P | Cholesterol (CHOL) | כולסטרול Serum | סרום | Chemistry analyser COBAS 6000 | --- | |
| 104 | A | P | Chloride (CL) | Chloride (CL) Serum | סרום | Chemistry analyser COBAS 6000 | --- | |
| 105 | A | P | Creatine phospho Kinase (CPK) | Creatine phospho Kinase (CPK) Serum | סרום | Chemistry analyser COBAS 6000 | --- | |
| 106 | A | P | Creatinine (CRE) | Creatinine (CRE) Serum | סרום | Chemistry analyser COBAS 6000 | --- | |
| 107 | A | P | Creatinine clearance (CRE.CL) | Creatinine clearance (CRE.CL) Serum + Urine | סרום + שתן | Calculation Computer Calculation | --- | |
| 108 | A | P | Direct Bilirubin (D.BIL) | Direct Bilirubin (D.BIL) Serum | סרום | Chemistry analyser COBAS 6000 | --- | |
| 109 | A | P | Bilirubin Total (T.BIL) | Bilirubin Total (T.BIL) Serum | סרום | Chemistry analyser COBAS 6000 | --- | |
| 110 | A | P | Diastase – Amylase (DIA) | Diastase – Amylase (DIA) Serum | סרום | Chemistry analyser COBAS 6000 | --- | |
| 111 | A | P | Gamma Glutamyl Transpeptidase (GGTP) | Gamma Glutamyl Transpeptidase (GGTP) Serum | סרום | Chemistry analyser COBAS 6000 | --- | |

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| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 112 | A | P | Glucose (GLU) | Glucose (GLU) | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 113 | A | P | Glucose Urine (GLUU) | Glucose Urine (GLUU) | Urine | שתן | Chemistry analyser | COBAS 6000 | --- |
| 114 | A | P | Glucose (GLU) | Glucose (GLU) | CSF | נוזל עמוד שידרה | Chemistry analyser | COBAS 6000 | --- |
| CSF=Cerebro Spinal Fluid | | | | | | | | | |
| 115 | A | P | Glucose Tolerance Test (GLU.TT) | Glucose Tolerance Test (GLU.TT) | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 116 | A | P | Lactic Acid (LAC.AC) | Lactic Acid (LAC.AC) | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 117 | A | P | Lactic Acid (LAC.AC) | Lactic Acid (LAC.AC) | CSF | נוזל עמוד שידרה | Chemistry analyser | COBAS 6000 | --- |
| 118 | A | P | Lactate Dehydrogenase (LDH) | Lactate Dehydrogenase (LDH) | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 119 | A | P | Lithium (LI) | Lithium (LI) | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 120 | A | P | Magnesium (MG) | Magnesium (MG) | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 121 | A | P | Potassium/Sodium (NA/K) | Potassium/Sodium (NA/K) | Serum | סרום | Chemistry analyser | COBAS 6000 | --- |
| 122 | A | P | Na/KU (Potassium / Sodium Urine) | Na/KU (Potassium / Sodium Urine) | Urine | שתן | Chemistry analyser | COBAS 6000 | --- |

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| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 123 | A | P | Phosphate (P) | זרחן Serum | סרום | Chemistry analyser | COBAS 6000 | --- | |
| 124 | A | P | Phosphate in Urine (PU) | זרחן בשתן Urine | סרום | Chemistry analyser | COBAS 6000 | --- | |
| 125 | A | P | Triglycerides (TG) | טריגליצרידים Serum | סרום | Chemistry analyser | COBAS 6000 | --- | |
| 126 | A | P | Protein Total (TP) | כלל חלבון Serum | סרום | Chemistry analyser | COBAS 6000 | --- | |
| 127 | A | P | Protein Total (TP) | כלל חלבון Urine | שתן | Chemistry analyser | COBAS 6000 | --- | |
| 128 | A | P | Protein Total (TP) | כלל חלבון CSF | נוזל עמוד שידרה | Chemistry analyser | COBAS 6000 | --- | |
| 129 | A | P | Uric Acid (UR.AC) | חומצת שתן Serum | סרום | Chemistry analyser | COBAS 6000 | --- | |
| 130 | A | P | Uric Acid Urine (UR.ACU) | חומצת שתן בשתן Urine | שתן | Chemistry analyser | COBAS 6000 | --- | |
| 131 | A | P | Uric Acid Clearance (UA.CL) | Uric Acid Clearance (UA.CL) Serum + Urine | סרום + שתן | Calculation | Computer Calculation | --- | |
| 132 | A | P | Urea | אוראה Serum | סרום | Chemistry analyser | COBAS 6000 | --- | |
| 133 | A | P | Urea Urine (UREAU) | אוראה בשתן Urine | שתן | Chemistry analyser | COBAS 6000 | --- | |

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| Chemical Testing, Autoanalysers | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 134 | A | P | Iron | ברזל Serum | סרום Chemistry | COBAS 6000 | --- | |
| 135 | A | P | C-Reactive Protein (CRP) | C-Reactive Protein (CRP) Serum | סרום Immunoturbidimetric | COBAS 6000 | --- | |

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



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Chemistry, General Biochemistry, Hemodynamics and Oxymetry | | | | | משפחת מוצרים: בריאות, רפואה - כימיה, ביוכימיה כללית, המודינמיקה ואוקסימטריה | | | | |
| Chemical Testing, Autoanalysers | | | | | בדיקות כימיות, שיטות באוטואנלייזרים | | | | |
| 136 | A | P | Carbon oxide (CO) | פחמן חד חמצני | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- |
| 137 | A | P | Carbon dioxide (PCO2) | פחמן דו חמצני | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- |
| 138 | A | P | Oxygen (PO2) | חמצן | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- |
| 139 | A | P | pH | PH | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- |
| 140 | A | P | Ionized calcium (ICA++) | Ionized calcium (ICA++) | Whole blood | דם מלא | Blood gas | AVL-OMNIS | --- |

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.



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

Schedule of Accreditation

Name and Address:

Organization name Hadassah Medical Organization
Laboratory name In Vitro Fertilization (IVF)
Sub division Ein-Karem hospital
Address P.O.Box 12000, Jerusalem 91120 Israel
Phone +972-2-677-7619
Fax +972-2-643-3337
E-Mail Einata@hadassah.org.il

| 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 - Fertility Andrology | | | | משפחת מוצרים: בריאות, רפואה - פריון, אנדרולוגיה | | | | | |
| Biological Testing, Sperm testing | | | | בדיקות ביולוגיות, בדיקת זרע | | | | | |
| 141 | A | P | Ejaculated sperm preparation | הכנת דגימת זרע | Sperm | זרע | N.A | Centrifuge and Laminar hood --- | N.A= Not applicable |
| 142 | A | P | Testicular and epididymal sperm preparation | הכנת תאי זרע שנשאבו מהאשך או יותרת האשך | Sperm | זרע | N.A | Microscope and Centrifuge and Laminar hood --- | |

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.



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Fertility Embryology | | | | משפחת מוצרים: בריאות, רפואה - פריון, אמבריולוגיה | | | | | |
| Biological Testing, IVF + Micromanipulation | | | | בדיקות ביולוגיות, מיקרומניפולציה + IVF | | | | | |
| 143 | A | P | Culture | תרבית Embryo | עובר N.A | Incubator | --- | | |
| 144 | A | P | Thawing | הפשרה Embryo | עובר N.A | Laminar hood | --- | | |
| 145 | A | P | Transferring into uterus | החזרה לרחם Embryo | עובר N.A | Laminar hood | --- | | |
| 146 | A | P | Egg fertilization (IVF, ICSI) | הפרית ביצית (בשיטת מיקרומניפולציה), IVF Sperm and eggs | זרע וביציות N.A | Micro-manipulation system (Microscope) and Laminar hood | --- | | |
| 147 | A | P | Freezing | הקפאה Embryo | עובר N.A | Planer and Laminar hood | --- | | |

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.



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

Schedule of Accreditation

Name and Address:

Organization name Hadassah Medical Organization
Laboratory name In Vitro Fertilization (IVF)
Sub division Mt. Scopus hospital
Address P.O.Box 24035, Jerusalem 91240 Israel
Phone +972-2-584-4643
Fax +972-2-584-4965
E-Mail batsheva@hadassah.org.il

| 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 - Fertility Andrology | | | | | משפחת מוצרים: בריאות, רפואה - פרייה, אנדרולוגיה | | | | |
| Biological Testing, Sperm testing | | | | | בדיקות ביולוגיות, בדיקת זרע | | | | |
| 148 | A | P | Ejaculated sperm preparation | הכנת דגימת זרע | Sperm | זרע | N.A | Centrifuge and Laminar hood --- | N.A= Not applicable |
| 149 | A | P | Testicular and epididymal sperm preparation | הכנת תאי זרע שנשאבו מהאשך או יותרת האשך | Sperm | זרע | N.A | Microscope and Centrifuge and Laminar hood --- | |

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.



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Fertility Embryology | | | | משפחת מוצרים: בריאות, רפואה - פריון, אמבריולוגיה | | | | | |
| Biological Testing, IVF + Micromanipulation | | | | בדיקות ביולוגיות, מיקרומניפולציה IVF + | | | | | |
| 150 | A | P | Culture | תרבית Embryo | עובר N.A | Incubator | --- | | |
| 151 | A | P | Thawing | הפשרה Embryo | עובר N.A | Laminar hood | --- | | |
| 152 | A | P | Transferring into uterus | החזרה לרחם Embryo | עובר N.A | Laminar hood | --- | | |
| 153 | A | P | Egg fertilization (IVF, ICSD) | הפריית ביצית (בשיטת מיקרומניפולציה), IVF Sperm and eggs | זרע וביציות N.A | Micro-manipulation system (Microscope) and Laminar hood | --- | | |
| 154 | A | P | Freezing | הקפאה Embryo | עובר N.A | Planer 10 | --- | | |

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.



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

Schedule of Accreditation

Name and Address:

Organization name Hadassah Medical Organization
Laboratory name Liver Unit
Sub division Ein-Karem hospital
Address P.O.Box 12000, Jerusalem 91120 Israel
Phone +972-2-677-8191
Fax +972-2-642-0338
E-Mail radler@hadassah.org.il

| 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 - Microbiology, Viruses | | | | | משפחת מוצרים: בריאות, רפואה - מיקרוביולוגיה, נגיפים | | | | |
| Biological Testing, Identification & Typing Molecular Methods PCR-Based Testing | | | | | בדיקות ביולוגיות, זיהוי ואפיון בשיטות מולקולריות מבוססות PCR | | | | |
| 155 | A | P | Virus: Hepatitis B DNA detection by Real Time PCR (quantitative) | Serum / Plasma | סרום/פלסמה | PCR-Real Time Abbott 2000sp Abbott 2000rt | --- | | |
| 156 | A | P | Virus: Hepatitis C RNA detection by Real Time PCR (quantitative) | Serum / Plasma | סרום/פלסמה | PCR-Real Time Abbott 2000sp Abbott 2000rt | --- | PCR= Polymerase Chain Reaction | |

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.



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Microbiology, Viruses | | | | | משפחת מוצרים: בריאות, רפואה - מיקרוביולוגיה, נגיפים | | | | | |
| Biological Testing, Non Culture Identification Typing - Immunoassays in Autoanalysers | | | | | בדיקות ביולוגיות, זיהוי ואפיון ללא תרבית - שיטות אימונוכימיות באוטואנלייזרים | | | | | |
| 157 | A | P | Virus: HCV (Hepatitis C Virus) Ab | Virus: HCV (Hepatitis C Virus) Ab | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | MEIA= Microparticle Enzyme Immuno Assay |
| 158 | A | P | Virus: Hepatitis A Ab (IgG) | Virus: Hepatitis A Ab (IgG, Total) | Plasma | פלסמה | MEIA | AxSYM | --- | |
| 159 | A | P | Virus: Hepatitis A Ab (IgM) | Virus: Hepatitis A Ab (IgM) | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |
| 160 | A | P | Virus: Hepatitis A Ab (quantitative) | Virus: Hepatitis A Ab (quantitative) | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |
| 161 | A | P | Virus: Hepatitis B Core Ab (IgM) | Virus: Hepatitis B Core Ab (IgM) | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |
| 162 | A | P | Virus: Hepatitis B Core Ab (Total) | Virus: Hepatitis B Core Ab (Total) | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |
| 163 | A | P | Virus: Hepatitis B e Ab | Virus: Hepatitis B e Ab | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |
| 164 | A | P | Virus: Hepatitis B e Ag | Virus: Hepatitis B e Ag | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |
| 165 | A | P | Virus: Hepatitis B Surface Ab | Virus: Hepatitis B Surface Ab | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |
| 166 | A | P | Virus: Hepatitis B Surface Ab (quantitative) | Virus: Hepatitis B Surface Ab (quantitative) | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |

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.



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Microbiology, Viruses | | | | משפחת מוצרים: בריאות, רפואה - מיקרוביולוגיה, נגיפים | | | | | | |
| Biological Testing, Non Culture Identification Typing - Immunoassays in Autoanalysers | | | | בדיקות ביולוגיות, זיהוי ואפיון ללא תרבית - שיטות אימונוכימיות באוטואנלייזרים | | | | | | |
| 167 | A | P | Virus: Hepatitis B Surface Ag | Virus: Hepatitis B Surface Ag | Serum / Plasma | סרום/פלסמה | MEIA | AxSYM | --- | |

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.

Date of issue 12.06.2013 Version No. 2

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



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 - Microbiology, Viruses | | | | | משפחת מוצרים: בריאות, רפואה - מיקרוביולוגיה, נגיפים | | | | | |
| Biological Testing, Non Culture Identification & typing - Manual Immunoassays | | | | | בדיקות ביולוגיות, זיהוי ואפיון ללא תרבית - שיטות אימונוכימיות ידניות | | | | | |
| 168 | A | P | LKM1 (Liver Kidney Microsomal type 1) Ab | LKM1 (Liver Kidney Microsomal type 1) Ab | Serum / Plasma | סרום/פלסמה | Elisa (Eurimmun) | Microplate reader | --- | |
| 169 | A | P | Virus: HCV (Hepatitis C Virus) Ab – verification | Virus: HCV (Hepatitis C Virus) Ab – verification | Serum / Plasma | סרום/פלסמה | Western blot by LIA | Orbital shaker | --- | LIA= Line Immuno Assay Chiron Riba, Innogenetics Inno-LIA |
| 170 | A | P | Virus: Hepatitis B Surface Ag | Virus: Hepatitis B Surface Ag | Serum / Plasma | סרום/פלסמה | Elisa (Murex) | Microplate reader | --- | |
| 171 | A | P | Virus: Hepatitis Delta Ab (Total) | Virus: Hepatitis Delta Ab (Total) | Serum / Plasma | סרום/פלסמה | Elisa (DiaSorin) | Microplate reader | --- | |

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

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Department: Testing Laboratory

ISO/IEC 17025

Accreditation No. 117

Appendix to Certificate No.

117-04

Schedule of Accreditation

| Item | Scope Type | Site | Materials / Products Tested | | Types of Test / Properties Measured | | Standard / Method | Opinion and Interpretation | Remarks |
|--|------------|------|-----------------------------|-----------------------------|---|--|-------------------|----------------------------|---------------------|
| Group of products: Health, Medicine - Microbiology, Viruses | | | | | משפחת מוצרים: בריאות, רפואה - מיקרוביולוגיה, נגיפים | | | | |
| Biological Testing, Non Culture Identification Typing - Immunoassays in Autoanalysers | | | | | בדיקות ביולוגיות, זיהוי ואפיון ללא תרבית - שיטות אימונוכימיות באוטואנלייזרים | | | | |
| 172 | A | P | Kamada preparations | Kamada preparations | Virus: HCV (Hepatitis C Virus) Ab | Virus: HCV (Hepatitis C Virus) Ab | MEIA | --- | באמצעות מכשיר AxSYM |
| 173 | A | P | Omxix preparations | Omxix preparations | Virus: Hepatitis A Ab (quantitative) | Virus: Hepatitis A Ab (quantitative) | MEIA | --- | באמצעות מכשיר AxSYM |
| 174 | A | P | Kamada & Omrix preparations | Kamada & Omrix preparations | Virus: Hepatitis B Surface Ab (quantitative) | Virus: Hepatitis B Surface Ab (quantitative) | MEIA | --- | באמצעות מכשיר AxSYM |
| 175 | A | P | Kamada & Omrix preparations | Kamada & Omrix preparations | Virus: Hepatitis B Surface Ag | Virus: Hepatitis B Surface Ag | MEIA | --- | באמצעות מכשיר AxSYM |



Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

Schedule of Accreditation

Name and Address:

Organization name Hadassah Medical Organization
Laboratory name Tissue typing and Immunogenetics
Sub division Ein-Karem hospital
Address P.O.Box 12000, Jerusalem 91120 Israel
Phone +972-2-677-7801
Fax +972-2-642-2403
E-Mail israels@hadassah.org.il

| 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 by Manual Immunoassays | | | | | בדיקות ביולוגיות, סיווג והצלבה של HLA בשיטות אימונוכימיות ידניות | | | | |
| 176 | A | P | Crossmatch | הצלבה Patient serum vs. lymphocytes of donor | סרום הנבדק כנגד לימפוציטים מהתורם | CDC | Microscope Centrifuge Elisa reader | --- | CDC = Compliment Dependent Cytotoxicity |
| 177 | A | P | Screen and PRA | Screen and PRA Patient serum | סרום הנבדק | Presence of HLA antibodies in serum by fluorescent beads | Vacuum device Centrifuge Luminex | --- | PRA = Panel Reactive Antibody |
| 178 | A | P | Serological Typing of HLA (Human Leukocyte antigens) Class I | Serological Typing of HLA (Human Leukocyte antigens) Class I Whole blood, spleen derived lymphocytes, lymphnodes derived lymphocytes | דם מלא, לימפוציטים נגזרים מהטחול, לימפוציטים נגזרים מבלוטות לימפה. | CDC – Complement dependent cytotoxicity Tissue typing | Centrifuge Microscope | --- | |

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

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Department: Testing Laboratory-Medical ISO 15189 Accreditation No. 117

Appendix to Certificate No. 117-04

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 | | | | | |
| 179 | A | P | Molecular HLA typing by OlerupPCR- SSP method | Molecular HLA typing by OlerupPCR- SSP method | DNA extracted from Whole blood, Buccal cells, bone marrow, cord blood, CVS דם מלא, תאים אורלים, מח עצם, דם טבורי, סיסי שליה | DNA amplification Tissue typing | Thermocycler | --- | Molecular HLA typing by Olerup method |
| 180 | A | P | Molecular HLA typing by Pelfreez PCR-SSP method | Molecular HLA typing by Pelfreez PCR-SSP method | DNA extracted from Whole blood, Buccal cells, bone marrow, cord blood, CVS דם מלא, תאים אורלים, מח עצם, דם טבורי, סיסי שליה | DNA amplification Tissue typing | Thermocycler | --- | Molecular HLA typing by Pelfreez method |
| 181 | A | P | Molecular HLA typing by Luminex | סיווג מולקולרי של HLA בשיטת ריצוף Luminex | DNA extracted from Whole blood, Buccal cells, bone marrow, cord blood, CVS דם מלא, תאים אורלים, מח עצם, דם טבורי, סיסי שליה | DNA amplification Tissue typing | Thermocycler Luminex | --- | |

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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Appendix to Certificate No. 117-04

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 | | | | |
| 182 | A | P | DNA extraction | הפקת DNA Whole blood, Buccal cells, bone marrow, cord blood, CVS | דם מלא, תאים אורלים, מח עצם, דם טבורי, סיסי שליה | Salting out Magnetic beads | Centrifuge Magnapure | CVS=Chorionic Villus Sampling |
| 183 | A | P | Genetic markers for post transplant monitoring | סמנים גנטיים לניטור אחר השתלה DNA extracted from Whole blood, Buccal cells, bone marrow, cord blood, CVS | דם מלא, תאים אורלים, מח עצם, דם טבורי, סיסי שליה | DNA amplification STR | Thermocycler, Sequencer ABI 3100 | STR=Short Tandem Repeats |
| 184 | A | P | Molecular HLA typing by sequencing | סיווג מולקולרי של HLA בשיטת ריצוף DNA extracted from Whole blood, Buccal cells, bone marrow, cord blood, CVS | דם מלא, תאים אורלים, מח עצם, דם טבורי, סיסי שליה | DNA amplification Tissue typing | Thermocycler, Sequencer ABI 3130XL Centrifuge | |
| 185 | A | P | Paternity testing (court ordered) | בדיקת אבהות (עפ"י דרישת בית משפט) DNA extracted from Whole blood, Buccal cells, bone marrow, cord blood, CVS | דם מלא, תאים אורלים, מח עצם, דם טבורי, סיסי שליה | STR analysis | Thermocycler Sequencer | STR- Short Tandem Repeats ampFstr Idetifiler Roche |

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.