

**List of Biologicals / Biotherapeutic
Under Testing
(Labs Accredited & Notified)
at
National Institute of Biologicals as on 21.08.14**

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S. No.	Name of Laboratories	Current Biologicals	Biologicals to be taken up
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	Total	141	102

Bacterial Vaccines

Biologicals to be taken up

1. BCG for immunotherapy
2. Haemophilus influenzae b TT Conjugate (Hib)
3. Meningococcal Polysaccharide bivalent vaccine
4. Meningococcal Polysaccharide tetravalent vaccine
5. Meningococcal A conjugate vaccine
6. Typhoid Vi Polysaccharide vaccine
7. BCG Vaccine (freeze dried)

n = 07

Biochemical kits

Current Biochemical kits

1. Glucose Reagent
2. Glucose Test Strips

n = 02

Biochem Kits to be taken up

QUANTITATIVE ELISA BASED CANCER MARKER KITS

1. Prostate specific antigen (PSA)
2. Alpha-foetoprotein (AFP)
3. Cancer antigen 125 (CA125)
4. Cancer antigen 15-3 (CA15-3)
5. Cancer antigen 19-9 (CA 19-9)
6. BRCA-1
7. BRCA-2
8. Carcinoembryonic antigen (CEA)
9. Thyroglobulin (Tg)
10. TGF β
11. Tumor Necrosis Factor
12. Fetoprotein (non hepatic carcinoma)

RAPID TESTS

13. HbA_{1c} (Boronate affinity based rapid cartridges/Strips)

n = 13

Blood Grouping Reagents

Current Biologicals

1. Anti-A Polyclonal
2. Anti-B Polyclonal
3. Anti-AB Polyclonal
4. Anti-D (IgM) Polyclonal
5. Anti-D (IgG) Polyclonal
6. Anti-D (IgM+IgG) Polyclonal
7. Anti-A Monoclonal -Bulk and Concentrate
8. Anti-B Monoclonal -Bulk and Concentrate
9. Anti-AB Monoclonal
10. Anti-D (IgM) Monoclonal
11. Anti-D (IgG) Monoclonal
12. Anti-D (IgM+IgG) - Bulk and Concentrate
13. Anti-A1 (Lectin)
14. Anti-H (Lectin)
15. Anti Human Globulin
16. Bovine Serum Albumin
17. Gel Card Forward grouping

Biologicals to be taken up

1. Anti Kp^b (Monoclonal)
2. Anti Lu^b (Monoclonal)
3. Anti Lu^a (Monoclonal)

n= 03

Blood Grouping Reagents

Current Biologicals

18. Gel Card forward & Reverse grouping
19. Gel Card for New borns
20. Anti-Fy^a Reagent
21. Anti-Fy^b Reagent
22. Anti-Jk^a Reagent
23. Anti-Jk^b Reagent
24. Gel Card Anti-A1 (Lectin)
25. Gel Card Anti-H (Lectin)
26. Gel Card for direct anti globulin test
27. Microplate for forward & Reverse grouping.
28. Anti-K Reagent
29. Anti-k Reagent
30. Blood Grouping Cards
31. Sera/Gel card for AHG & C3d,
32. Anti Kp^a Reagent
33. Anti Le^a Reagent
34. Anti Le^b Reagent
35. Anti Pi Reagent

n=35

Blood Products

Current Biologicals

1. Human albumin(4.5%,5.0%,20%, 25%)
2. Normal immunoglobulin Intravenous(10 ml,40 ml, 50 ml, 100 ml)
3. Normal immunoglobulin Intramuscular(2ml)
4. Human Coagulation Factor - VIII
5. Human Prothrombin complex
6. Human fibrinogen
7. Anti- RhD Immunoglobulin (Monoclonal)
8. Plasma protein Fraction
9. Fibrin sealant kit (1 ml, 2.0 ml, 5.0 ml)
10. Human Coagulation Factor IX
11. Anti- RhD Polyclonal Immunoglobulin (Intravenous)
12. Anti-Rh D Polyclonal Immunoglobulin (Intramuscular)
13. Tetanus Immunoglobulin
14. Anti-Thrombin
15. FEIBA-Factor Eight Inhibitor By pass activity
16. Recombinant Coagulation factor- VIII

n=16

Biologicals to be taken up

1. Recombinant Coagulation Factor-IX
2. Human Coagulation Factor – XI
3. Human Coagulation Factor - VII
4. SD-treated Plasma
5. Human Albumin injection iodinated125
6. Human Hepatitis A Immunoglobulin
7. Human Measles immunoglobulin
8. Human Rubella immunoglobulin
9. Human Tetanus immunoglobulin
10. Human Varicella immunoglobulin(IM)
11. Human Varicella immunoglobulin (IV)
12. Anti Human Lymphocyte immunoglobulin
13. Platelet Derived Growth Factor

n=13

Enzymes & Hormones

Current Biologicals

Enzymes:

1. Streptokinase injection (C)
2. Urokinase injection (C)
3. Heparin Sodium injection (C)
4. Recombinant Streptokinase injection

Hormones:

5. Human Chorionic Gonadotropin injection (C)
6. Menotropin (Human Menopausal Gonadotropin) injection (C)
7. Urofollitropin injection (C)
8. Recombinant Human Follicle stimulating Hormone Injection (R)
9. Recombinant Human Somatropin injection

n = 09

Biologicals to be taken up

1. Heparin Calcium Injection (C)
2. Enoxaparin Sodium injection (C)
3. Hyaluronidase injection (C)
4. Protamine Sulphate injection (C)
5. Tissue plasminogen activator (tPA) injection (R)
6. Cerezyme (R)
7. Fabrazyme (Agalsidase beta) (R)
8. Rasburicase (R)
9. Aldurazyme (Laronidase) (R)
10. Aglucosidase alfa for injection (R)
11. Thyroid hormones (Thyroxine) (C)
12. Progesterone Injection (C)
13. Thyrotropin Alpha Injection (R)

n = 13

Immunodiagnostic kits

Current Biologicals

1. HIV 1&2 Ab Rapid
2. HIV 1&2 Ab ELISA,
3. HIV 1&2 Ab Western Blot
4. HIV 1&2 Ab ELFA
5. HIV 1&2 Ab LIA
6. HIV 1&2 Ab CLIA
7. HBsAg Rapid
8. HBsAg ELISA
9. HBsAg Neutralization
10. HBsAg ELFA
11. HBsAg CLIA
12. HCV Ab Rapid
13. HCV Ab ELISA
14. HCV Ab Western Blot
15. HCV Ab LIA
16. HCV Ab RIBA
17. HCV Ab ELFA
18. HCV Ab CLIA
19. Syphilis RPR
20. Syphilis TPHA
21. Syphilis Rapid
22. Syphilis ELISA
23. Syphilis CLIA

Biologicals to be taken up

1. Malaria
2. Dengue
3. Leishmania

n = 03

Immunodiagnostic kits

Current Biologicals

24. HIV Ag-Ab Rapid
25. HIV Ag-Ab ELISA
26. HIV Ag-Ab ELFA
27. HIV Ag-Ab CLIA
28. HCV Ag-Ab ELISA
29. HCV Ag-Ab ELFA
30. HIV-2Ab Western Blot
31. HBc Total ELISA
32. HBc Total ELFA
33. HBc Total CLIA
34. HBc IgM ELISA
35. HBc IgM ELFA
36. HBc IgM CLIA
37. HBe Ag-Ab ELISA
38. HBe Ag-Ab ELFA
39. HBe Ag-Ab CLIA
40. Anti HBs ELISA
41. Anti HBs ELFA
42. Anti HBs CLIA
43. HIV,HCV,HBV Combo Rapid
44. HIV TP Combo Rapid
45. HIV Ag CLIA
46. HIV Ag ELFA

n = 46

Recombinant Products

Current Biologicals

1. Soluble insulin (Regular)
2. Isophane insulin (NPH)
3. Biphasic Isophane Insulin (25/75)
4. Biphasic Isophane Insulin (30/70)
5. Biphasic Isophane Insulin (50/50)
6. Insulin Lispro
7. Insulin Lispro & Insulin Lispro Protamine Suspension
Mixed in 25/75 Mix
8. Insulin Lispro & Insulin Lispro Protamine Suspension
Mixed in 50/50 Mix
9. Insulin Aspart
10. Insulin Aspart & Insulin aspart protamine suspension
Mixed in 30/70 mix
11. Insulin Aspart & Insulin aspart protamine suspension
Mixed in 50/50 mix
12. Insulin Glargine
13. Insulin Glulisine
14. Insulin Detemir
15. Exenatide
16. Liraglutide (Glucagon like Peptide-1)
17. Insulin Degludec
18. rh- Insulin bulk

Biologicals to be taken up

1. Interferon alpha 2a
2. GM-CSF Granulocyte macrophage colony stimulating factor
3. Peglyated EPO
4. Peglyated IFN
5. Pegylated G-CSF
6. Dulaglutide, Albiglutide, Lixisenatide (Glucagon like Peptide -1)
7. Non-Injectable Insulin
8. Darbepoietin alpha
9. PDGF platlet-derived growth factor
10. EGF Epidermal growth factor
11. Interleukin 2

n = 11

Recombinant Products

Current Biologicals

19. rh. Erythropoietin injection
20. rh. Erythropoietin Bulk
21. Interferon beta 1a.
22. rh. Granulocyte Colony Stimulating Factor (GCSF)
23. Insulin Aspart Bulk
24. Insulin Lispro Bulk
25. Parathyroid hormone (PTH)
26. Interferon alpha 2b
27. Insulin Degludec / Insulin Aspart

n = 27

Viral Vaccines

Current Biologicals

1. Rabies immunoglobulin (human)
2. Hepatitis B Immunoglobulin (intramuscular)
3. Hepatitis B Immunoglobulin (Intravenous)

n = 03

Biologicals to be taken up

1. Human Papilloma virus vaccine
2. Poliomyelitis vaccine (Inactivated)
3. Japanese Encephalitis Vaccine (Human) (inactivated)
Mouse brain / cell culture
4. Rotavirus vaccine (live attenuated)
5. Varicella vaccine (live attenuated)
6. Measles vaccine, Live
7. Rubella vaccine, Live
8. Measles, Mumps & Rubella vaccine (MMR) Live
9. Rabies Vaccine (human)
10. Rabies antiserum (Equine)

n = 10

Newer Laboratories Getting Established

Allergens

Biologicals to be taken up

1. Cockroach allergens
2. Moth Allergens
3. Fungal allergens
4. House dust allergens
5. Pollen allergens
6. Moulds

n = 06

Nucleic Acid Testing (NAT)

Current Biologicals

1. Human Immuno Deficiency Virus-1 test Kit for Viral load determination
2. Hepatitis B Virus test kit for Viral load determination
3. Hepatitis C Virus test kit for Viral load determination

n = 03

Biologicals to be taken up

1. Human Immunodeficiency Virus-1 test kit for blood donor screening
2. Hepatitis B Virus test kit for blood donor screening
3. Hepatitis C Virus test kit for blood donor screening
4. Multiplex (HBV, HCV & HIV-1) test kit for blood donor screening

n = 04

Therapeutic monoclonal antibodies

Biologicals to be taken up

1. Rituximab
2. Trastuzumab
3. Bevacizumab
4. Panitumumab
5. Infliximab
6. Etanercept
7. Canakinumab
8. Itolizumzb
9. Basiliximab
10. Omalizumab
11. Cetuximab
12. Ranibizumab
13. Tocilizumab
14. Natalizumab
15. Denosumab
16. Nimotuzumzb
17. Gemtuzumab ozogamicin
18. Daclizumab
19. Abciximab

n = 19