



IstoGen P.C.

Molecular Diagnostics Laboratories

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DIAGNOSTIC TEST

SUITABLE SPECIMEN TYPE

Somatic Mutations	
Detection of BRAF V600E mutation	Biopsy, Paraffin-Embedded Tissue (FFPE), Fresh Tissue, Fresh Frozen Tissue
KRAS mutation Panel (7 mut @codons 12, 13)	
NRAS mutation Panel (10 mut @codons 12, 13, 61, 146)	
EGFR mutation Panel (3 mut: L858R, 746-750Del, T790M)	
Detection of JAK2 V617F mutation	Biopsy, Paraffin-Embedded Tissue (FFPE), Fresh Tissue, Fresh Frozen Tissue, WB EDTA

Genetic Diseases	
Breast Cancer: Panel of 8 frequent mutations at BRCA1 (7 mut) and BRCA2 (1 mut) genes	WB EDTA, Buccal Swab
Cystic Fibrosis: Detection of ΔF508 mutation	
Ankylosing Spondylitis: Detection of HLA B27 polymorphism	

Human Papilloma Virus (HPV)	
Detection and Typing of high-risk HPV types 16 and 18	Cervical Swab, Fluid Cytology Sample (ThinPrep), Mucosal Biopsy Material, Urethral Epithelial Swab, Epithelial Cells Scrapings, Semen, Prostatic Fluid, Urine
Detection and Typing of low-risk HPV types 6 and 11	
Concurrent Detection and Typing of low-risk HPV types 6, 11 and high-risk HPV types 16, 18	
Detection and Typing of 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)	
Concurrent Detection and Typing of 2 low risk (6, 11) and 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)	

Human Herpes Viruses	
Detection of Herpes Simplex Virus 1 (HSV-1)	Epithelial Cells Scrapings, Saliva, Semen, Prostatic Fluid, Urine, Serum, Plasma *, Leucocytes, WB EDTA
Detection of Herpes Simplex Virus 2 (HSV-2)	
Detection and Typing of Herpes Simplex Viruses 1 & 2 (HSV-1/2)	
Detection of Cytomegalovirus (CMV)	Epithelial Cells Scrapings, Saliva, Semen, Prostatic Fluid, Urine, Serum, Plasma *, Leucocytes, WB EDTA
Quantification of CMV viral load	
Detection of Epstein-Barr Virus (EBV)	Serum, Plasma *, WB EDTA, Saliva, Nasal Mucosa Swab, Epithelial Cells Scrapings
Quantification of EBV viral load	
Detection of Varicella Zoster Virus (VZV)	Epithelial Cells Scrapings, Saliva, Semen, Prostatic Fluid, Urine, Serum, Plasma *, Leucocytes, WB EDTA
Detection Panel for Human Herpes Viruses (HSV-1/2, CMV, EBV, VZV)	Epithelial Cells Scrapings, Saliva, Semen, Prostatic Fluid, Urine, Serum, Plasma *, Leucocytes, WB EDTA

Sexually Transmitted Infections	
Detection of <i>Mycoplasma hominis</i> bacterium	Epithelial Cells Scrapings, Semen, Prostatic Fluid, Urine
Detection of <i>Mycoplasma genitalium</i> bacterium	
Detection and Typing of <i>M.hominis/M.genitalium</i> bacteria	
Detection of <i>Ureaplasma parvum</i> bacterium	Cervical Swab, Urethral Swab, Semen, Prostatic Fluid, Urine
Detection of <i>Ureaplasma urealyticum</i> bacterium	
Detection and Typing of <i>U.parvum/U.urealyticum</i> bacteria	
Detection of <i>Trichomonas vaginalis</i> protozoan parasite	Cervical Swab, Urethral Swab, Pharyngeal Swab, Conjunctival Swab, Semen, Prostatic Fluid, Urine
Detection of <i>Neisseria gonorrhoeae</i> bacterium	
Detection of <i>Chlamydia trachomatis</i> bacterium	
Detection Panel for <i>T.vaginalis, N.gonorrhoeae, C.trachomatis</i>	
Detection of <i>Candida albicans</i> fungus	Saliva, Urine Epithelial Cells Scrapings
Detection of <i>Gardnerella vaginalis</i> bacterium	
Detection Panel for <i>C.albicans</i> and <i>G.vaginalis</i>	
Detection of Syphilis bacterium <i>Treponema pallidum</i>	Epithelial Cells Scrapings, Tissue Fluid (from erosive and ulcerative lesions of the skin and mucous membranes)
Detection Panel for <i>Mycoplasma spp., Ureaplasma spp., T.vaginalis, N.gonorrhoeae, C.trachomatis</i>	Cervical Swab, Urethral Swab, Semen, Prostatic Fluid, Urine

Viral Hepatitis and AIDS	
Detection of Hepatitis B Virus (HBV)	Plasma *
Quantification of HBV viral load	
Detection of Hepatitis C Virus (HCV)	Plasma *
Quantification of HCV viral load	
Detection of Human Immunodeficiency Virus (HIV)	Plasma *
Quantification of HIV viral load	

Pregnancy Infections	
Detection of Rubella Virus	Serum, Plasma *
Detection of <i>Toxoplasma gondii</i> bacterium	Serum, Plasma *
Detection of Parvovirus B19	Plasma *, Amniotic Fluid, Sputum, Swab
Quantification of Parvovirus B19 viral load	

Polyoma Viruses	
Detection of JC Virus (JCV)	WB EDTA, Plasma *, Serum, Urine, Cerebrospinal Fluid, Biopsy
Detection of BK Virus (BKV)	
Concurrent Detection of JCV and BKV Viruses	

Respiratory Infections	
Detection of <i>Mycobacterium tuberculosis</i>	WB EDTA, Serum, Plasma *, Biopsy, Liquor, Urine, Bronchopulmonary Lavage, Sputum, Synovial Fluid
Detection of Pneumonia bacterium <i>Mycoplasma pneumoniae</i>	WB EDTA, Biopsy/Tissue, Swab, Bronchopulmonary Lavage
Detection of Pneumonia bacterium <i>Chlamydia pneumoniae</i>	
Detection Panel for Pneumonia bacteria (<i>M.pneumoniae</i> and <i>C.pneumoniae</i>)	
Detection of Influenza A Virus	Nasopharyngeal Swab, Aspirate, Bronchopulmonary Lavage, Nasal Wash, Biopsy/Tissue (from parenchymatous organs, trachea, lung, brain)
Detection of Influenza B Virus	
Detection Panel for Influenza A & B Viruses	
Detection of Swine Influenza H1N1	
Detection of human Respiratory Syncytial Virus (hRSV)	Swab, Biopsy/Tissue, Sputum, Bronchopulmonary Lavage, Tracheal Lavage
Detection of <i>Bordetella pertussis</i> bacterium	Posterior Nasopharyngeal Swab, Oropharyngeal Swab

Male Infertility	
Detection of AZF microdeletions in Y-chromosome	WB EDTA, Buccal Swab

Gastric Ulcer	
Detection of <i>Helicobacter pylori</i> bacterium	Biopsy/Stomach Tissue

Thrombophilia/Cardiovascular Diseases Factors	
Factor II Prothrombin (20210 G>A)	WB EDTA, Buccal Swab
Factor V Leiden (1691 G>A)	
MTHFR (677 C>T)	
MTHFR (1298 A>C)	
Thrombophilia Panel A (4 polymorphisms) (Factor II Prothrombin, Factor V Leiden, MTHFR C677T & A1298C)	
Thrombophilia Panel B (12 polymorphisms) (F2 Prothrombin, F5 Leiden & His1299Arg, F13 Val34Leu, MTHFR C677T & A1298C, PAI-1 -675 5G>4G, B-Fibrinogen -455 G>A, ACE I/D, ITGB3 Leu33Pro, ApoB Arg3500Gln, ApoE E2,E3,E4)	
Folic Acid Metabolism Panel (4 polymorphisms) (MTHFR C677T & A1298C, MTR 2756 A>G, MTRR 66 A>G)	

Next Generation Sequencing (NGS) tests	
All NGS tests	WB EDTA

- Samples must be stored **immediately** after collection, either at 4°C for **24 hours (12 hours for HIV, Rubella, Influenza, hRSV, M.pneumoniae, C.pneumoniae)**, or at -20°C/-80°C for longer time periods (OA EDTA strictly at 4°C).
- Samples must always be shipped at temperatures ≤4°C (OA EDTA strictly at 4°C) and **within the abovementioned time limits**.
- **WB EDTA:** Whole Blood with EDTA (tube/vacutainer with purple/lavender cap).
- * **Plasma** isolation from WB EDTA must be performed **within 6 hours** from blood collection, by centrifugation at **1500g for 20 minutes**. Plasma can be stored at 4°C for **3 days (12 hours for HIV)** or at -20°C for **1 month**.