

TARGET-VALIDATED AND CHARACTERIZED IVD ANTIBODIE FOR PATHOLOGY AND IMMUNOTHERAPY

<u>RAbMonoTM</u> (Rabbit Monoclonal) and MonoMAbTM (Mouse Monoclonals) Markers



Zeta designs and develops tumor-specific biomarkers using cutting edge technology to uniquely select the immunogens for our famed RAbMonoTM (Rabbit Monoclonal) and MonoMabTM (Monospecific monoclonal antibodies). Zeta's RAbMonoTM and MonoMabTM Antibodies are produced through the hybridoma and recombinant technologies.

Zeta offers over 375 individual primary antibodies of high-qualityFDA registered, IVD certified for Pathology/IHC. These antibodies are carefully chosen and developed to consistently produce staining on formalin-fixed paraffin-embedded tissue (FFPE) sections. Our antibodies are carefully screened and rigorously tested to provide unparalleled consistency and reliability in immunohistochemical staining. Every antibody developed in-house goes through Design and Development processes as required by ISO 13485. These antibodies are tested and validated by leading laboratories globally and external quality control institutions like the NordicQC.

All of our antibodies work on formalin-fixed paraffin embedded (FFPE) tissue sections. As an **ISO 13485:2016 certified** biomedical company,allourantibodyclonesarescientificallyselectedtofitthe needofclinicalimmunohistochemicallaboratories. Ourprimaryantibodies are manufactured by FDA certified GMP facilities interUSAand purified by affinity chromatography with >99% purity.

TARGET-VALIDATED AND CHARACTERIZED IVD ANTIBODIES

Androgen Receptor (AR) Rabbit Monoclonal Antibody

Anti-rabbit: Clone ZR334, Cat # Z2640

Androgen Receptor is a member of the superfamily of ligand responsive transcription regulators. Androgen Receptor has been reported in a diverse range of human tumors including osteosarcoma, and in prostatic carcinoma androgen receptor expression may be of clinical relevance. Androgen Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.



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Human prostate tissue stained with anti-AR (Clone ZR334)

*Reference:

- 1. Collins LC, et al. Mod Pathol. 2011; 24:924-31.
- 2. Rahmani AH, et al. Int J Mol EpidemiolGenet. 2013; 4:150-55.

3. Leach, DA, et al. Cancers (Basel). 2017; 9: pii: E10.

ATRX Rabbit Monoclonal Antibody Anti-rabbit: Clone ZR10, Cat # Z2014

Transcriptional regulator ATRX, also known as ATPdependent helicase ATRX, X-linked helicase II, or Xlinked nuclear protein (XNP), is a protein that in humans is encoded by the ATRX gene. Transcriptional regulator ATRX contains an ATPase /helicase domain, and thus it belongs to the SWI/SNF family of chromatin remodeling proteins. ATRX is required for deposition of the histone variant H3.3 at telomerases and other genomic repeats. These interactions are important for maintaining silencing at these sites. ATRX mutations are common in CNS gliomas.

Human glioblastoma stained with anti-ATRX. Note: Tumor cells negative (loss) and endothelial cells positive

* References

2. Liau JY, et al. Am J Surg Pathol.2015;39:236-44.

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^{1.} Casar-Borota O, et al. Am J Surg Pathol. 2017; 41:1238-1246.

TARGET-VALIDATED AND CHARACTERIZED IVD ANTIBODIES

Bcl-6 Rabbit Monoclonal Antibody Anti-rabbit: Clone ZR280, Cat # Z2658

Recognizes a protein of 95kDa, which is identified as Bcl-6. Antibody to bel-6 is helpful in a number of diagnostic settings: (1) In the differential diagnosis of small B-cell lymphoma. Follicular lymphoma will show bcl-6 (and CD10) positivity whereas other small B-cell lymphomas are usually negative. (2) Bcl-6 is an important prognostic marker in diffuse large B-cell lymphomas (DLBCL), where CD10, bcl-6 and MUM1/IRF4 are used to identify germinal center and activated B-cell phenotypes. (3) Bcl-6 can be valuable in distinguishing classical Hodgkin lymphoma from nodular lymphocyte predominant Hodgkin lymphoma (NLPHL). The Reed-Sternberg cells of classical Hodgkin lymphoma are bcl-6 negative whereas the large ("L&H") cells of NLPHL are bcl-6 positive. In contrast, anti-Bcl-6 rarely stains mantle-cell lymphoma and MALT lymphoma.

*Reference:

- 1. Falini B, et al. Ann Oncol. 1997;2: 101-4.
- 2. Dogan A, et al. Am J Surg Pathol. 2000; 24:846-52.
- 3. Carbone A, et al. Hum Pathol. 2010; 41:621-31.

CD38 Rabbit Monoclonal Antibody Anti-rabbit: Clone ZR351, Cat # Z2610

CD38 is a transmembrane protein that is highly expressed on thymocytes. It is also present on activated T-cells and terminally differentiated B-cells (plasma cells). Other reactive cells include NK cells, monocytes, macrophages and dendritic cells. CD38 may be detected on cells from multiple myeloma, ALL (B and T) and some AML.

*Reference:

- 1. Quintanilla-Martinez L, et al. Am J Surg Pathol. 1992;16(11):1075-84.
- 2. Camacho FI, et al. Am J Surg Pathol. 2003;27(6):762-71.
- 3. Rodig SJ, et al. Am J Surg Pathol. 2008;32(1):113-22.



Human tonsil stained with anti-Bcl-6 antibody (Clone ZR280)



Human tonsil stained with anti-CD38 antibody (Clone ZR351)

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CD30 Rabbit Monoclonal Antibody Anti-rabbit: Clone ZR248, Cat # Z2489

Recognizes a single chain glycoprotein of 105/120kDa, identified as CD30/Ki-1. In Hodgkin's disease, CD30/Ki-1 antigen is expressed by mononuclear-Hodgkin and multinucleated Reed-Sternberg cells. It is also expressed by the tumor cells of a majority of anaplastic large cell lymphomas as well as by a varying proportion of activated T and B cells. This MAb distinguishes large cell lymphomas derived from activated lymphoid cells from histiocytic malignancies and lymphomas derived from resting and precursor lymphoid cells or from anaplastic carcinomas.

*References

- 1. Schwarting R, et al. Blood. 1989; 74:1678-89.
- 2. George DH, et al. Am J Surg Pathol. 2003; 27:487-93.
- 3. Hedvat CV, et al. Hum Pathol. 2002; 33:968-74.



Human Hodgkin lymphoma stained with anti-CD30 (clone ZR248)

DPC4 (SMAD4) Rabbit Monoclonal Antibody Anti-rabbit: Clone ZR281, Cat # Z2596

SMAD4, also called SMAD family member 4, or DPC4 (Deleted in Pancreatic Cancer-4) is a highly conserved protein present in all human tissues. Signaling from the ligand-activated membrane receptor serine/threonine kinases to nuclear targets is mediated by DPC4. Upon ligand binding, the receptors of the TGF- β family phosphorylate SMAD proteins (SMAD1 and SMAD2). These proteins then move into the nucleus, where they activate transcription. To carry out this function, the receptor activated SMAD1 and 2 require association with DPC4, also known as SMAD4. SMAD4/DPC4 is also implicated as a tumor suppressor, since it is inactivated in more than half pancreatic of



Human pancreatic ductal adenocarcinoma stained with anti-DPC4 (Clone ZR281). Note tumor glands negative, surrounding lymphocytes positive.

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carcinomas and to a lesser extent in a variety of other cancers. The lack of SMAD4 expression is present in approximately 80% of cases of pancreatic

*Reference:

1. Iacobuzio-Donahue CA, et al. Am J Surg Pathol. 2000; 24:1544-8.

2. Hornick JL, et al. Am J Surg Pathol. 2005; 29:381-9.

adenocarcinoma, but rarely in endometrial (0%), colorectal (0%), ovarian (3%), lung (0%), breast (2%) adenocarcinomas, and malignant melanoma (4%). SMAD4 is an important marker for confirming a diagnosis of pancreatic adenocarcinoma.

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FoxP1 Rabbit monoclonal Antibody Anti-rabbit: Clone: ZR333, Cat # Z2639

Forkhead box protein P1 (FOXP1) is a transcriptional repressor. It plays an important role in the specification and differentiation of lung epithelium. FOXP1 protein plays an important role in the specification and differentiation of lung epithelium, also acts cooperatively with FOXP4 to regulate lung secretory epithelial cell fate and regeneration by restricting the goblet cell lineage program. FOXP1 is useful in subclassification of DLBCL and a high cutoff (\geq 80%) for FOXP1 is needed to achieve high specificity for the ABC subtype.



Human lymph node stained with anti-CD79a antibody (Clone ZR237)

*References:

- 1. Alizadeh AA, et al. Nature. 2000; 403:503-11.
- 2. Choi WW, et al. Clin Cancer Res. 2009; 15:5494-5502.
- 3. Nyman H, et al. Mod Pathol. 2009;2 2:1094-1101.

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GATA 3 Rabbit monoclonal Antibody Anti-rabbit: Clone: ZR65, Cat # Z2375

GATA-3 is a transcription factor that in humans is encoded by the GATA3 gene. This 50 kDa nuclear protein regulates the development and subsequent maintenance of a variety of human tissues, including hematopoietic cells, skin, kidney, mammary gland, and the central nervous system. Among several other roles, GATA-3 involved in luminal cell differentiation in the mammary gland and appears to control a set of genes involved in the differentiation and proliferation of breast cancer. The expression of GATA-3 is associated with the expression of estrogen receptor-alpha (ER) in breast cancer. GATA-3 has been shown to be a novel marker for bladder cancer.



Normal breast tissue stained with GATA3 (clone ZR65)

References

- 1. Higgins JP, et al. Am J Surg Pathol. 2007; 31:673-680.
- 2. Liu H, et al. Am J Clin Pathol. 2012; 138:57-64.

3. Joulin V, et al. EMBO J. 1991; 10: 1809-16.

INI-1 Rabbit monoclonal Antibody Anti-rabbit: Clone: ZR282, Cat # Z2597

The INI-1 gene (SWI/SNF-related matrix-associated actin-dependent regulator of chromatin subfamily B member 1) is a protein that in humans is encoded by the SMARCB1 gene. The protein encoded by this gene is part of a complex that relieves repressive chromatin structures, allowing the transcriptional machinery to access its targets more effectively. This gene has been found to be a tumor suppressor, which is often mutated or deleted in malignant rhabdoid tumors, epithelioid sarcoma, and some malignant peripheral nerve sheath (MPNST) tumors.

Human epithelioid sarcoma stained with anti-INI-1 antibody (Clone ZR282)

*Reference:

- 1. Bourdeaut F, et al. J Pathol. 2007; 211:323-30.
- 2. Fowler DJ, et al. Fetal Pediatr Pathol. 2006; 25:159-68.

3. Haberler C, et al. Am J Surg Pathol. 2006; 30:1462-8.

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LEF 1 Rabbit monoclonal Antibody Anti-Rabbit: Clone: ZR336, Cat # Z2642

Lymphoid Enhancing Factor 1 (LEF1) is a transcription factor that belongs to the TCF/LEF family. LEF1 participates as a regulator in Wnt signaling pathways. LEF1 is an important factor in lymphopoiesis and is expressed normally in T and pro-B cells but not expressed in mature B cells. Strong nuclear expression of LEF1 has been observed in majority of chronic lymphocytic leukemia/small lymphocytic lymphoma cases and LEF1 is not detected in other small B cell lymphomas. Anti-LEF1 may be used as an aid for differentiation of chronic lymphocytic leukemia/small lymphocytic lymphoma from other small B cell lymphomas.



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Human tonsil stained with anti-LEF 1 (Clone ZR336)

*References:

1. Nikuševa-Martić T, et al. Pathol Oncol Res. 2013; 19:545-51.

2. Cribier B, et al. J Cutan Pathol. 2006; 33:1-9.

3. Onaindia A, et al. Am J Surg Pathol. 2016; 40:378-85.

Myeloperoxidase (MPO) Rabbit monoclonal Antibody Anti-Rabbit: Clone: ZR341, Cat # Z2647

The heme protein myeloperoxidase (MPO) is a major component of azurophilic granules of neutrophils and polymorphonuclear leukocytes. Optimal oxygendependent microbiocidal activity depends on MPO as the critical enzyme for the generation of hypochlorous acid and other toxic oxygen products. iMPO mRNA is abundant in human promyelocytic HL-60 and mouse myeloid leukemia NFS-60cells. MPO is expressed at high levels in circulating neutrophils and monocytes but is not detectable in microglia, brain-specific macrophages or normal brain tissue.

*References:

- 1. Pinkus GS, et al. Mod Pathol. 1991; 4:733-41.
- 2. Arber DA, et al. Am J Clin Pathol. 1996; 106:462-8.
- 3. Chang CC, et al. Am J Clin Pathol. 2000; 114:807-11.



Human bone marrow stained with anti-Myeloperoxidase antibody (Clone ZR341)

All of our antibodies work on formalin-fixed paraffin embedded (FFPE) tissue sections. As an **ISO 13485:2016 certified** biomedical company,allourantibodyclonesarescientificallyselectedtofitthe needofclinicalimmunohistochemicallaboratories. Our primary antibodiesare manufactured by FDA certified GMP facilities interUSAandpurified by affinity chromatography with >99% purity.

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MLH-1 Rabbit Monoclonal Antibody Anti-rabbit: Clone: ZR259, Cat # Z2573

The MLH-1 repair of mismatch DNA is essential to maintaining the integrity of genetic information over time. An alteration of microsatellite repeats is the result of slippage owing to strand misalignment during DNA replication and is referred to as microsatellite instability (MSI). These defects in DNA repair pathways have been related to human carcinogenesis. The importance of mismatch repair genes became apparent with the identification of the genetic basis for hereditary nonpolyposis colon cancer (HNPC). MSH-2 is involved in the initial cognition of mismatch nucleotides during the replication mismatch repair process. It is thought that after MSH-2 binds to a mismatched DNA duplex it is joined by a heterodimer of MLH-1 and PMS-2, which together help facilitate the later steps in mismatch repair.

Colon adenocarcinoma stained with MLH-1. Note: tumor cells negative and infiltrating lymphocyte positive

*Reference:

1. Räschle M, et al. J Biol Chem. 1999; 274:32368-75.

2. Garg K, et al. Am J Surg Pathol. 2009;33(6):925-33.

3. Meijer JW, et al. Am J Surg Pathol. 2008;32(8):1246-51.

NeuN Rabbit Monoclonal Antibody Anti-rabbit: Clone: ZR338, Cat # Z2644

NeuN antibody specifically recognizes the DNA-binding, neuron-specific protein NeuN, which is present in most CNS and PNS neuronal cell types of all vertebrates tested. Immunohistochemically detectable NeuN protein first appears at developmental timepoints that correspond with the withdrawal of the neuron from the cell cycle and/or with the initiation of terminal differentiation of the neuro. Strong nuclear staining suggests a nuclear regulatory protein function; however, no evidence currently exists as to whether the NeuN protein antigen has a function in the distal cytoplasm or whether it is merely synthesized there before being transported back into the nucleus. No difference between protein isolated from purified nuclei and whole brain extract on immunoblots has been found.

*Reference:

1. Edgar MA, et al. Arch Pathol Lab Med. 2008; 132:500-9.

2. Ulbright TM, et al. Mod Pathol. 2010; 23:972-80.



Human cerebrum tissue stained with NeuN antibody (Clone ZR338)

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^{3.} Lopes MB, et al. Am J Surg Pathol. 2017; 41:586-595.

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OCT-4 Rabbit Monoclonal Antibody Anti-rabbit: Clone: ZR266, Cat # Z2580

Octamer-binding transcription factor 4 (OCT-4), is a transcription factor protein that is encoded by the Pou5f1 gene and is part of the POU (Pit-Oct-Unc) family. OCT-4 consists of an octamer motif, a particular DNA sequence of AGTCAAAT that binds to their target genes and activates or deactivates certain expressions. It plays a vital role in determining the fates of both inner mass cells and embryonic stem cells and has the ability to maintain pluripotency throughout embryonic development. OCT-4 is an excellent immunohistochemical marker for seminoma and dysgerminoma of various origins.

*Reference:

- 1. Browne P, et al. Am J Clin Pathol. 2003; 120:767-77.
- 2. García-Cosío M, et al. Mod Pathol. 2004; 17:1531-8.
- 3. Gibson SE, et al. Am J Clin Pathol. 2006; 126:916-24.

Olig2 Rabbit Monoclonal Antibody Anti-rabbit: Clone: ZR340, Cat # Z2646

Olig2, a basic helix-loop-helix transcription factor, is involved in oligodendroglial specification. Olig2 expression has been reported in most glial tumors, such as oligodendrogliomas and astrocytomas. Although more than half of glioblastomas are positive for Olig2, expression is very weak in terms of both percentage of labeled cells and intensity. No Olig2 expression has been found in the non-glial tumors including neuroepithelial ependymomas, subependymomas, tumors, medulloblastomas, and nonneuroepithelial tumors, such as CNS lymphomas, meningiomas, schwannomas, atypical teratoid/rhabdoid tumor. and hemangioblastomas. Compared to the strong staining seen in glioma samples, a weak expression is observed in non-tumoral brain tissue (gliosis).

*Reference:

1. Mokhtari K, et al. Neuropathol Appl Neurobiol. 2005; 31:62-9.

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Human cerebrum tissue stained with Olig2 antibody (Clone ZR340)





Seminoma tumor stained with OCT-4 antibody (Clone ZR266)

^{2.} Otero JJ, et al. J Neurooncol. 2011; 104:423-38.

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TARGET-VALIDATED AND CHARACTERIZED IVD ANTIBODIES FOR PATHOLOGY AND IMMUNOTHERAPY

p120 Catenin Rabbit Monoclonal Antibody Anti-rabbit: Clone: ZR316, Cat # Z2620

Alpha-catenin and beta-catenin bind to the intracellular domain of E-cadherin while p120 catenin binds Ecadherin at a juxta-membrane site. p120 is a proliferationassociated nucleolar protein found in most human malignant tumors, but not in resting normal cells. In colorectal cancer the altered localization of p120 catenin corresponds with loss of cytoplasmic localization of Ecadherin. Studies have shown accurate categorization of ductal vs. lobular neoplasia in the breast was achieved with p120 staining. Studies also have shown that altered expression of p120 catenin antibody predicts poor outcome in invasive breast cancer.

*Reference:

- 1. Reynolds AB, et al. Oncogene. 1992; 7:2439-45.
- 2. Dabbs DJ, et al. Am J Surg Pathol. 2007; 31:427-37.
- 3. Jawhari AU, et al. J Pathol. 1999; 189:180-5.

p21^{WAF1} Rabbit Monoclonal Antibody Anti-rabbit: Clone: ZR288, Cat # Z2602

This MAb recognizes a 21kDa protein, identified as the p21WAF1 tumor suppressor protein. This MAb is highly specific to p21 and shows no cross-reaction with other closely related mitotic inhibitors. p21WAF1 is a specific inhibitor of cdk's and a tumor suppressor involved in the pathogenesis of a variety of malignancies. The expression of this gene acts as an inhibitor of the cell cycle during G1 phase and is tightly controlled by the tumor suppressor protein p53. Its expression is induced by the wild type, but not mutant, p53 suppressor protein. Normal cells generally display a rather intense nuclear p21 expression. Loss of p21 expression has been reported in many carcinomas (gastric carcinoma, non-small cell lung carcinoma, thyroid carcinoma).

*Reference:

- 1. DiGiuseppe JA, et al. Am J Pathol. 1995; 147:884-8.
- 2. Xie HL, et al. World J Gastroenterol. 2004; 10:1125-31.

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Human breast lobular carcinoma stained with p120 (ZR316). Note: cytoplasmic staining of tumor cells and membranous staining of normal ductal cells (low left)





Carcinoma tissue stained with p21^{WAF1} antibody (Clone ZR288)

^{3.} Stein JP, et al. J of Natl Cancer Inst. 1998; 90:1072

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Rb (Retinoblastoma) Mouse Monoclonal Antibody Anti-mouse: Clone: 1F8, Cat # Z2651

Recognizes a 105kDa phosphoprotein, identified as retinoblastoma (Rb) gene product. Its epitope is localized between aa 703-772. It shows no cross reaction with p107 or p130. It specifically stains the nuclei of BT-20 cells and primary human foreskin fibroblast (HFF) cells. Retinoblastoma gene product plays a key role in cell cycle control. It has been identified as a tumor suppressor gene whose loss of its function leads to tumor development. It is widely expressed in a variety of human tissues including breast, esophageal, squamous cell and cervical carcinoma.



Human colon stained with anti-Rb antibody (Clone 1F8)

*Reference:

- 1. Mariño-Enriquez A, et al: Am J Surg Pathol. 2017;41(2):234-244.
- 2. Chen BJ, et L: Am J Surg Pathol. 2012;36(8):1119-28.
- 3. Subhawong AP, et al: Am J Surg Pathol. 2009;33(2):163-75.

Steroidogenic Factor (SF-1) Rabbit Monoclonal Antibody Anti-rabbit: Clone: ZR350, Cat # Z2590

The Steroidogenic Factor 1 (SF-1) protein is a transcription factor involved in sex determination by controlling activity of genes related to the reproductive glands or gonads and adrenal glands. This protein is encoded by the NR5A1 gene, a member of the nuclear receptor subfamily, located on the long arm of chromosome 9 at position 33.3. SF-1 is expressed in the cortex of normal adrenal gland, adrenal cortical adenomas and carcinomas. It is also positive in sex-cord stromal tumors of testicle and ovarian origins.

*Reference:

1. Zhao C, Vinh TN, et al. Am J Surg Pathol. 2009; 33:354-66.

2. Sangoi AR, et al. Am J Surg Pathol. 2011; 35:678-86.



Human adrenal gland stained with anti-SF-1 antibody (Clone ZR350)

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^{3.} McCluggage WG, et al. Am J Surg Pathol. 2013; 37:1458-9.

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TIA-1 Rabbit Monoclonal Antibody Anti-rabbit: Clone: ZR284, Cat # Z2599

The T cell intracellular antigen 1 (TIA-1) is a 17-kDa cytoplasmic granule associated protein also designated as GMP-17, for granule membrane protein of 17 kDa. The GMP-17/TIA-1 molecule is expressed in cells possessing cytolytic potential and could be involved in the signaling cascade of Fas (CD95)-mediated apoptosis. Within hematopoietic cell lines, the 2G9 monoclonal antibody (mAb) reacts with about 90% of CD16+, 50 - 60% of CD8+, and less than 10% of CD4+ normal peripheral blood lymphocytes. It reacts with almost all monocytes and granulocytes. This antibody also reacts with CD4+ activated T-cell clones, activated NK cell clones, and Con activated thymocytes, but not with B lymphocytes or B-cell lines.



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Human Spleen stained with anti-TIA-1 (Clone ZR284)

*Reference:

- 1. Dukers DF et al. J Clin Pathol 1999; 52:129-36.
- 2. Kanavaros P et al. Anticancer Res 1999; 19:1209-16.
- 3. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. Villanova, PA 1991; 7(9). Order code M29-P.

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