

WHERE THERE IS A WILL THERE IS A WAY

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Issue 1



Dr. Hema Purandarey is a professional with vision & dreams. She puts her best efforts in completing them. She is not only the pioneer in establishing 1st Cytogenetics lab in India and offering these tests for patient care but also got 1st NABL accreditation for any Cytogenetics lab in India.

In her endeavour to offer better quality, she aspired for College of American Pathologists (CAP) accreditation. CAP is one of the prestigious International accreditation which takes in to account for technical quality of the lab and also covers overall safety & hygiene and quality in all the processes in the lab.

To fulfill the dream of Dr. Hema, each member of the cytogenetics team put sincere efforts & hard work under the guidance of Dr. Hema & Dr. Monika. Under the supervision of Dr. Monika, National Manager-Quality Systems, the Cytogenetics team successfully faced CAP audit on 14th January, 2010. Piramal Diagnostics Services Pvt. Ltd.

expects to become one of the leading labs with CAP accreditation of Cytogenetics in Western India. This will be a major achievement and will instill a confidence that we are second to none in offering the best Cytogenetics results to our patients. All the good wishes to Dr. Hema's lab for achieving soon this distinction and all the best for her future endeavors.

The Molecular Biology laboratory is the Center of Excellence located at G.K. Marg, Lower Parel, Mumbai. It has the prestigious -CAP (College of American Pathologists) and NABL accreditation. It caters to all the molecular tests covering infectious and hemato-oncology tests, from all across the country with more than 50-60 samples being processed daily.

Molecular Lab



The Molecular laboratory is well equipped with all the essential infrastructure required for molecular testing. It has the BSL type 2 facility with dedicated areas demarcated into three main areas i.e. Pre PCR, PCR and Post PCR areas

- Pre PCR area 1 consists of common room.
- Pre PCR area 2 consists of DNA isolation room.
- Pre PCR area 3 consists of RNA isolation room.
- PCR area consists of room for reagents & PCR master mix preparation and PCR amplification.
- Post PCR area consists of PCR product / amplicon detection room.
- The DNA, RNA and PCR areas are equipped with BSL type 2 biosafety cabinets with HEPA filters.

All the molecular tests are conducted under strict sterile conditions. As a measure of quality control, every batch of PCR assay is run with a positive, negative and an internal control to rule out any kind of false positive and false negative results.

The Molecular Biology Laboratory is divided into two subdivisions:

- 1) Infectious
- 2) Hemato-Oncology

The molecular tests done for infectious diseases are as follows:

- 1) TB PCR-
 - a) TB DNA PCR is done on Real Time PCR platform and it detects and differentiates between Mycobacterium tuberculosis Complex (MTC) and Mycobacterium other than tuberculosis (MOTT). This assay detects both active and dormant infection.
 - b) TMA (GeneProbe) is a FDA approved assay that detects 16s rRNA gene transcript by transcription mediated amplification with product detection performed via chemiluminescence. TMA detects only Mycobacterium tuberculosis Complex (MTC). This assay detects only active infection.
- 2) HIV qualitative (including HIV Proviral) and quantitative PCR
- 3) HBV qualitative and quantitative PCR
- 4) HCV qualitative and quantitative PCR
 - a) Quantitative PCR is done for detection and monitoring of HIV, HBV and HCV viral loads in respective patients. They are done on Abbott m2000rt platform which is FDA approved.
 - b) Qualitative PCR is gel based PCR and it detects presence or absence of HIV, HBV and HCV infection. This methodology is also used for detection of HIV Proviral which is done to detect early HIV infection much before antibodies to HIV virus are detected in blood. It is done in i) newborn infants and children less than 2 years of age born to HIV positive mothers, and ii) in patients who had accidental needle stick injury or any other exposure.

5) HBV genotyping

6) HCV genotyping

Both HBV and HCV genotyping are gel based PCRs and genotype specific primers are used.

7) CMV Qualitative PCR

8) Dengue Qualitative PCR

9) Chikungunya Qualitative PCR

10) EBV Qualitative PCR

All these viruses are detected by gel based PCR and is useful in the rapid diagnosis of the disease and in effective monitoring of clinical course as well as response to therapy.

1) HSV Qualitative PCR- It's a nested PCR and detects both HSV 1 and 2.

2) HPV Qualitative PCR – Detects high risk group HSV subtypes like 16 and 18.

The molecular tests done for Hemato-oncology cases are as follows:

1) BCR/ABL qualitative and quantitative PCR in Chronic Myeloid Leukemia (CML).

2) PML/RARA qualitative PCR in Acute Promyelocytic Leukemia (APML).

3) AML1/ETO qualitative PCR in Acute Myeloid Leukemia- AML M2

CML and APML with the associated genetic translocations have specific treatment with a good prognosis and therefore detection of these genetic translocations is essential for monitoring of these patients and to assess response to treatment.

4) JAK2 qualitative PCR in Chronic Myeloproliferative Disorder other than CML.

5) Factor V Leiden qualitative PCR – This test is done in patients with history of thrombosis and predisposing risk factors.

New tests to be started-



The laboratory is in the process of standardizing and starting new additional tests like

1) AML Multiplex PCR – For detection of following genes: PML/RARA, AML1/ETO, CBFB/MYH11

2) ALL Multiplex PCR – For detection of following genes: BCR/ABL, E2A/PBX, MLL/AF4, TEL/AML1.

3) Multiplex PCR for detection of genes associated with Thrombophilia i.e. Factor V Leiden (R506Q), Factor II (Prothrombin G 20210A) and MTHFR (677C>T) (methylenetetrahydrofolate reductase).

Flow cytometry tests:

Besides molecular tests, the following tests are conducted by flow cytometry:

1) CD3/CD4/CD8 enumeration – This test is advised for monitoring of therapy in HIV patients.

2) HLA B27 – This test is advised in patients with Ankylosing Spondylitis and other autoimmune disorder because of association of HLAB27 with these diseases.

3) Immunophenotyping of acute leukemias and chronic lymphoproliferative disorders. – To subtype leukemias and lymphomas.

4) PNH Analysis – To detect PNH clones in all cases of aplastic anaemia.

5) CD34 Enumeration- To enumerate optimal CD34 counts required for stem cell transplantation.

Bone Marrow Aspiration reporting and cytochemistry:

Peripheral blood and bone marrow aspiration reporting is also done for all hematological cases. Morphological reporting is supplemented by cytochemistry tests like Myeloperoxidase (MPO), Leukocyte Alkaline Phosphatase (LAP), Non specific esterase (NSE) and Tartrate resistant acid phosphates (TRAP).

Quality Control Program and Accreditation:

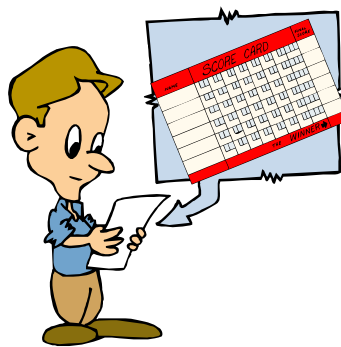
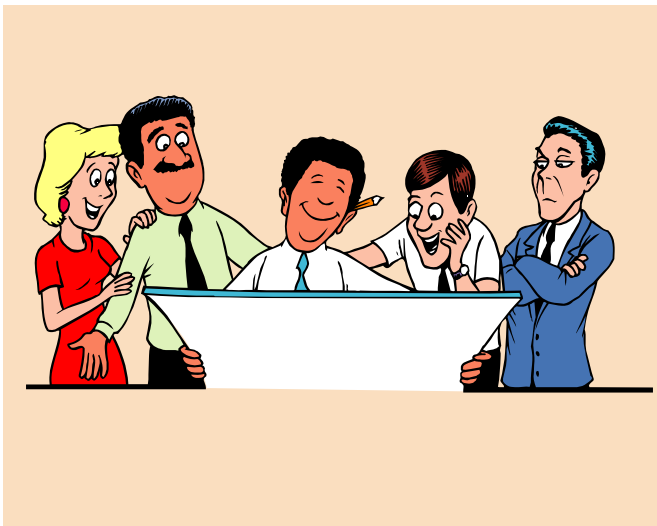
The laboratory periodically participates in internal and external quality control programs like CAP

Proficiency Survey and Interlaboratory Comparison. It has been successful in clearing all the audits conducted by CAP and NABL Accreditation bodies.

Training programs:

The laboratory conducts regular training programs for MSc Biotech students. Each student is given 3-6 months project as part of their dissertation. During this period the students undergo training in various aspects of molecular techniques and have hands on experience.

HR



We will now start receiving the scores cards for each Center. Effective February, the facilitation process by HR will start - on how to read the scorecards, its interpretation and also the way forward - The process of action planning with their teams. We look forward to your active support and participation in building PDSL a highly engaged and a world class workplace.



Last year in November 2009 we began our journey of employee engagement in PDSL using the Gallup Q12 methodology. At the outset, Management would like to thank each one of you for the enthusiasm shown in participating in this survey

