

Case Study

DIRA Assay Testing for Daratumumab Clinical Trials

Details Reflex Assay

Daratumumab-Specific Immunofixation Electrophoresis Reflex Assay (DIRA) was developed using a mouse anti-daratumumab antibody, and evaluated for specificity, limit of sensitivity, and reproducibility

Key Achievements

- Successful development DIRA
- Great collaboration between client and Cerba Research scientist
- Assay approved by FDA
- Results published in peer-reviewed article (Clinical Chemistry and Laboratory Medicine (CCLM)): "Monitoring Multiple Myeloma Patients Treated with Daratumumab: Teasing Out Monoclonal Antibody Interference"

Timeline

Q4 '15



Start

Dec '20



Anticipated End

Challenges

Therapeutic mAbs interfere with patient assessments, giving the impression that the patient will remain sick and never get a complete negative immunofixation. This falsely affects the overall efficacy of the study drug. Therefore, the client was searching to create an assay that could circumvent this issue and can be used as a valid tool to identify resolution of the disease and hence the efficacy of the drug.

Study Details

Study Type: Batch study

Trials: Multiple Myeloma clinical trials

Samples Per Patient: ~ 2.500 samples tested

DIRA Testing Serum Sample:

- Method: Immunofixation
- Instrument: Hydrasys and Hydrasus
- Manual and Qualitative
- TAT: 5 Working Days
- Lab: CRI (Ghent, Belgium)
- Scientist: Dominique Slaets

SPF and IFE Testing

Patients with low-level (<5 g/L) or negative SPE but repeated positive IgGκ IFE were flagged as having potential daratumumab interference, and were utilized for validation and DIRA testing.

Successes

The collaboration between our in-house scientist and the sponsor led to the creation of a new assay (DIRA) which can inform clinical outcomes by distinguishing daratumumab from endogenous M-protein by IFE, and can be used without having any interference issues. This assay was pivotal to the success of the trial and the drug, and the assay itself has been approved by the FDA. This indicates how scientific discussions are key to evaluating treatments and the success of a trial.

