

**26<sup>th</sup> January 2016**, National Health Service Quality Control North West (QCNW) Liverpool Labs are to perform monoclonal antibody stability trials, utilising deltaDOT Ltd technology and expertise to aid the study.

The medical world is being revolutionised by a new class of drug. Not based on chemicals, these new drugs are biological and are man-made versions of the antibodies that form the backbone of our immune system. Scientists can make antibodies that attach to proteins that are part of a disease process. If they attach to an important protein they can prevent it performing the disease function. These antibodies are called monoclonals (mAbs) and are increasingly being used by the NHS.

The complex nature of monoclonal antibodies requires an array of tests to be performed to demonstrate their stability. As part of the test regime, QCNW Liverpool is using deltaDOT's HPCE-512TC technology and utilising their expertise to develop the associated test protocols. The overall aim of such studies is to enable extended shelf life to be provided for patient specific preparations of monoclonal antibodies, which will enable more efficient use of NHS resources.

The use of deltaDOT's HPCE-512TC technology may then allow rationalised testing to be carried out for on-going quality control of preparations. This exciting project is a perfect validation of deltaDOT's technology and working ethos. Providing the technology and then working in partnership with the end-user to maximise their usage of it fits perfectly with the way deltaDOT work.

deltaDOT are extremely proud to be working with a world-class organisation like the NHS. QCNW Liverpool has carried out a number of stability studies on compounded mAb preparations, developing their knowledge and expertise over a 10 year period. Extended stability data on such preparations allows them to be prepared in controlled Hospital Pharmacy Aseptic Units, reducing risks to patients and offering efficiency savings, through reduced waste. As well as carrying out such studies for hospitals in the NW of England, QCNW Liverpool has also undertaken studies for hospitals outside this region and for industry clientele.

The complex nature of mAb's requires a wide spectrum of tests to be carried out to establish stability of the preparations. The addition of Capillary Gel Electrophoresis and Capillary Zone Electrophoresis has offered QCNW Liverpool an increased range of tests to establish overall stability of the preparations and may potentially allow a more rationalised approach to the tests performed for such studies. The ability to develop this additional area of analysis with the close co-operation of deltaDOT has offered exciting developments for the service.

#### **Notes to editors:**

##### **About NHS QCNW Labs Ltd**

QCNW Liverpool is a NHS regional specialty service providing comprehensive and leading edge Pharmaceutical Quality Assurance Services to NHS Trusts, Foundation Trusts, and Mental Health Trusts in the North West of England. As part of the overall healthcare team, their aim is to work with others to assure the quality of medicines, and to contribute to the minimisation of risks to NHS patients of receiving defective medicines. These aims are achieved by the application of appropriate systems of quality assurance, audit, and quality control to the purchasing, manufacturing/preparation, and management of medicinal products in hospitals.

**Find out more at:** [www.qcnw.nhs.uk](http://www.qcnw.nhs.uk)

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##### **About deltaDOT Ltd**

deltaDOT has developed and commercialised highly innovative Biotechnology instrumentation.

The analytical technology is based on an innovative approach to Capillary Electrophoresis (**CE**). deltaDOT's patented multipoint sensor system together with the proprietary computing algorithms gives superior resolution, accuracy and repeatability.

This is High Performance Capillary Electrophoresis (**HPCE**) at its best - Label Free Intrinsic Imaging (**LFII**<sup>®</sup>).

This technology has found successful applications in detection, separation and analysis of proteins, nucleic acids, carbohydrates, viruses and bacteria, drugs, chemicals and a wide range of other analytes.

**Find out more about deltaDOT Ltd at:** <http://www.deltadot.com>

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