

Application Case Study – LipoScience, Inc., Raleigh, NC

MS-3 Laser Scanners Deliver Seamless Automation for Lipoprotein Measurement in the Vantera® Clinical Analyzer

Customer Profile

LipoScience is an in vitro diagnostic company that provides personalized medical results based on the analysis of lipoproteins. The company, headquartered in Raleigh, North Carolina, is a pioneer in the use of nuclear magnetic resonance (NMR) to measure the quantity of lipoprotein particles in blood samples. The results of these measurements provide clinicians with the information they need to manage the treatment of cardiovascular disease, diabetes, and pre-diabetes.

LipoScience's FDA-approved Vantera Clinical Analyzer is poised to revolutionize lipoprotein analysis by employing radio frequency signals within a strong magnetic field to identify and quantify multiple subclasses of lipoprotein particles within minutes, eliminating the need for assay-specific chemical reagents in sample processing.

The Challenge

During the design phase of the Vantera Clinical Analyzer product realization, LipoScience recognized that it would be necessary to maintain positive, error-free identification of each specimen tube, test tube rack, and diluent throughout the analysis process. It was essential for the clinical analyzer to maximize sample throughput, tracking efficiency, repeatability, and 100% reporting accuracy while minimizing manual data entry and potential operator errors. Reliable identification of system components was required at four discrete points:

- Serum or plasma specimens in test tubes;
- Test tube racks;
- Up to six separate system diluents for the dilution of specimens prior to NMR analysis;
- Bulk rinse and wash fluid containers.

■ **Requirement:** Maximize throughput, tracking efficiency, and reporting accuracy of lipoprotein analysis within a NMR-based clinical analyzer.

■ **Project:** Integrate laser barcode scanners at four points within the clinical analyzer to identify and track items.



The Vantera Clinical Analyzer performs sophisticated NMR-based lipoprotein analysis and uses Microscan's MS-3 Laser Scanner to identify and track samples and diluents.

The Solution

Recognizing the need for a contract manufacturer familiar with in vitro diagnostic instrumentation, LipoScience turned to KMC Systems, a medical contract manufacturer with 30 years of proven experience designing and manufacturing clinical analyzers. KMC Systems also has a long history of collaboration with Microscan Systems, manufacturer of the MS-3 Laser Barcode Scanner, on clinical instrumentation projects. KMC chose Microscan's MS-3 for its speed, reliability, ultra-compact form factor, and proven record as an industry standard product uniquely optimized for lab automation. KMC Systems determined that these characteristics of the MS-3 would make it ideal for the identification and tracking requirements of the Vantera Clinical Analyzer.

■ **Solution:** Four embedded Microscan MS-3 Laser Scanners track barcodes on specimen tubes, specimen tube racks, diluent bottles, and bulk rinse and wash fluid containers.

■ **Result:** Assurance that all fluids in the system are accurately identified and tracked throughout the analysis process.

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KMC Systems integrated the MS-3 in the Vantera at the four discrete stages requiring identification of specific system components: test tubes, test tube racks, system diluents, and rinse and wash fluid containers. At the first stage, Vantera's direct tube sampler processes serum or plasma specimens from NMR LipoProfile® test tubes, standard red top tubes, and standard lavender top tubes – up to 200 specimen tubes at a time. The first MS-3 Laser Scanner identifies each test tube. Next, each test tube rack is identified by the second MS-3. Then the identity, lot number, and expiration date of each system diluent is confirmed by the third MS-3. Finally, the barcodes on the bulk rinse and wash fluid containers were scanned by the fourth MS-3.

The Benefits

The result of the partnership between LipoScience and KMC Systems is the Vantera Clinical Analyzer, an innovative clinical diagnostic product that uses NMR spectroscopic detection, proprietary signal processing algorithms, and sophisticated analysis software to identify and quantify lipoproteins – all while ensuring high rates of throughput, efficiency, repeatability, and reporting accuracy with embedded MS-3 Laser Scanners. LipoScience is confident that their newly-released Vantera Clinical Analyzer will play a major role in improving the quality of patient care.



Strategically placed MS-3 Laser Scanner identifies specimen samples.



The high-speed, ultra-compact MS-3 Laser Scanner can be embedded in a wide variety of clinical instruments.

OVERVIEW:

- **Customer:** LipoScience, Inc.
- **Industry:** Clinical Diagnostics
- **Application:** Analysis of lipoprotein particles in serum or plasma specimens
- **Products:** MS-3 Laser Barcode Scanner
- **Developer/Manufacturer:** KMC Systems, Inc.

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