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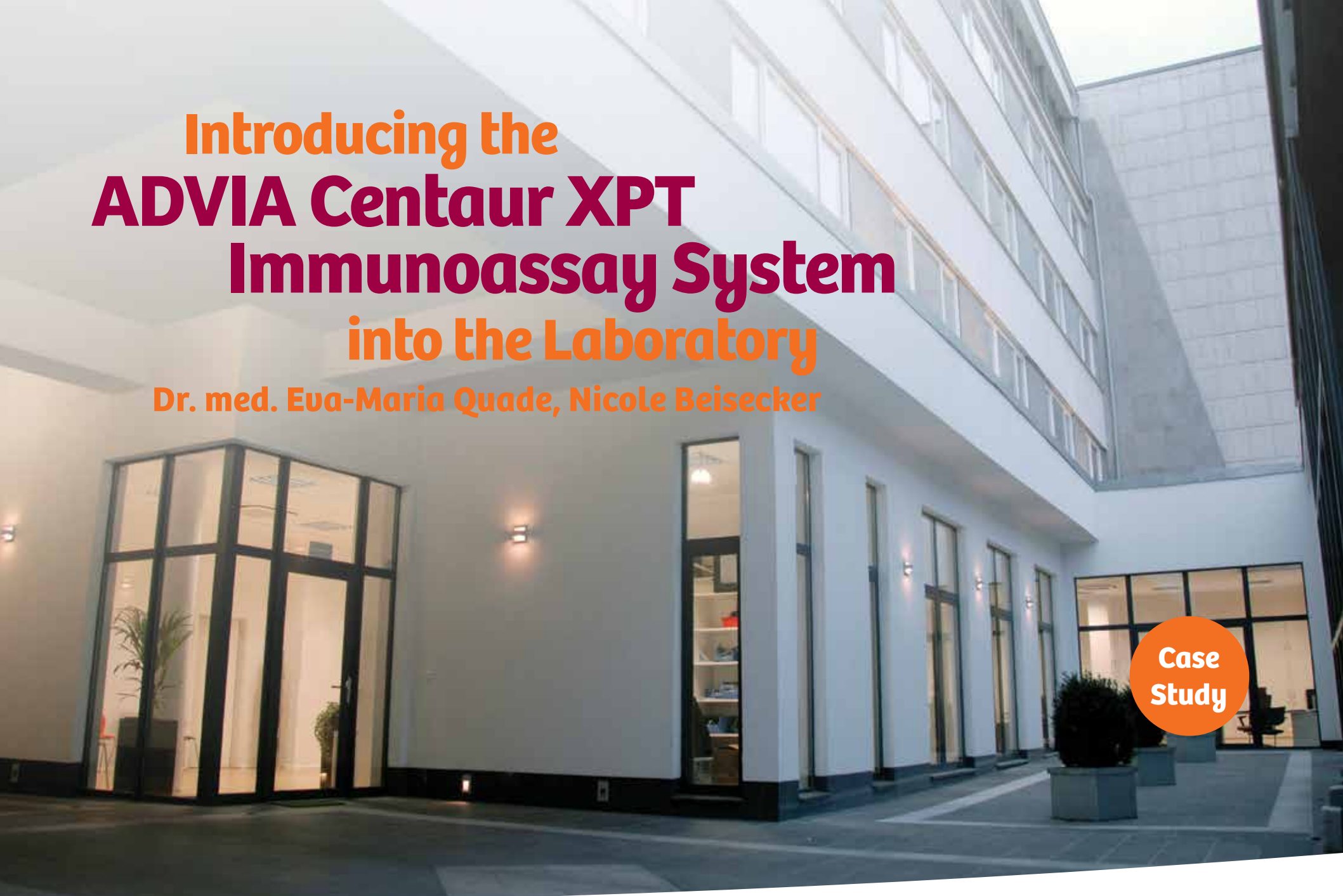
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Introducing the **ADVIA Centaur XPT** Immunoassay System into the Laboratory

Dr. med. Eva-Maria Quade, Nicole Beisecker

Case
Study



“The new system offers many advantages for laboratories willing to take the next step towards even higher laboratory efficiency, greater accuracy of patient results, and faster result reporting.”

Introducing the ADVIA Centaur XPT Immunoassay System into the Laboratory

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Our laboratory's major focus is ensuring that all our test results are consistently accurate and reproducible. Special efforts are taken to continually assess our workflow processes and optimize them with state-of-the-art science and technology. During the evaluation process for the new ADVIA Centaur XPT Immunoassay System, we concentrated on these aspects over a period of one year.

Analyzers connected to the ADVIA® LabCell® Automation Solution

- (4) ADVIA 1800 Clinical Chemistry Systems
- (1) ADVIA Chemistry XPT System
- (1) IMMULITE® 2000 XPI Immunoassay System
- (1) ADVIA Centaur® XPT Immunoassay System
- (3) ADVIA Centaur XP Immunoassay Systems

Photo: The fully automated ADVIA LabCell Automation Solution in use at our laboratory. In the front of the picture there are two sample managers with two decappers. Connected to the track are nine analyzers: four ADVIA 1800 Clinical Chemistry Systems, one ADVIA Chemistry XPT System, one IMMULITE 2000 XPI Immunoassay System, one ADVIA Centaur XPT Immunoassay System, and two ADVIA Centaur XP Immunoassay Systems. A technician is working with the middleware (CentraLink® Data Management System and LineMaster).

“The laboratory can now operate the system an additional 40 hours annually because of the reduction in maintenance time.”

Introduction

Laboratory Dr. Quade and Colleagues GmbH is a private mid-sized laboratory in Cologne, Germany. Nearly 4000 blood samples are transported by our couriers from physicians’ offices to the laboratory each day, mostly between noon and 7:00 p.m. (Figure 1). A team of clinical pathologists and lab technicians are involved in processing the samples at a rate of approximately 40,000 tests per day. Around 92% of the lab tests ordered by the physicians are performed and validated on the same day. The laboratory is accredited by Deutsche Akkreditierungsstelle (DAkkS) according to ISO DIN 15189 and ISO DIN 17025 (forensic drug testing) and by College of American Pathologists (CAP).

Since 2013, our laboratory has been a Siemens reference laboratory, and we are an early adopter of new Siemens systems and assays. In September 2014, the new ADVIA Centaur XPT Immunoassay System was installed for daily routine use and connected to the well-established ADVIA LabCell Automation Solution. In December 2015, ten analyzers were connected to the ADVIA LabCell Automation.

Laboratory Objectives

With the implementation of the new ADVIA Centaur XPT System, in combination with the ADVIA Centaur XP System within an existing LabCell Automation Solution, we aimed to achieve the following

- Enhanced connectivity to Siemens middleware (CentraLink Data Management System and LineMaster) and our own laboratory information system (LIS) with archive data-backup solutions and quality management
- Evaluation of workflow with the new ADVIA Centaur XPT System
- Method comparison and validation for ADVIA Centaur XP vs. ADVIA Centaur XPT System
- Investigation of further benefits for the operators

Results and Discussion

Automation connectivity of the ADVIA Centaur XPT System

The connection of the ADVIA Centaur XPT System to the ADVIA LabCell Automation Solution was completed quickly and smoothly in September 2014 (Photo above). Connectivity, sample processing and routing, and data transfer to the laboratory automation system (LAS) and (LIS) worked well from the beginning of the installation.



ADVIA LabCell Automation with ADVIA Centaur XPT System (left) and ADVIA Centaur XP System (right). Technically, it was no problem to combine both systems on ADVIA LabCell Automation.

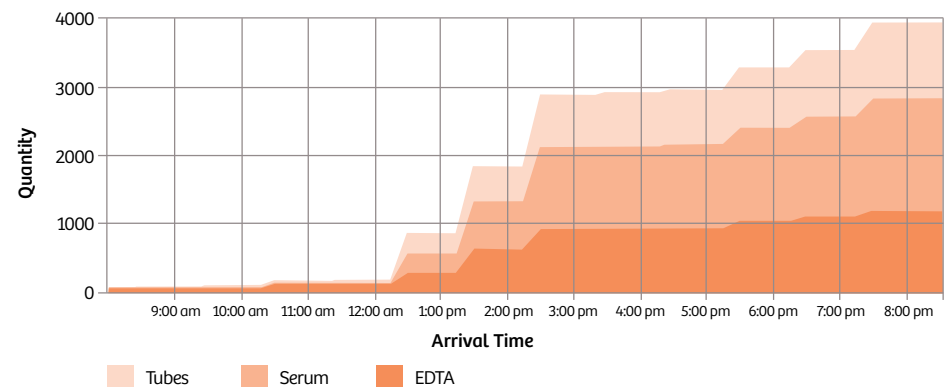


Figure 1. Typical pattern of daily sample arrivals at our laboratory.

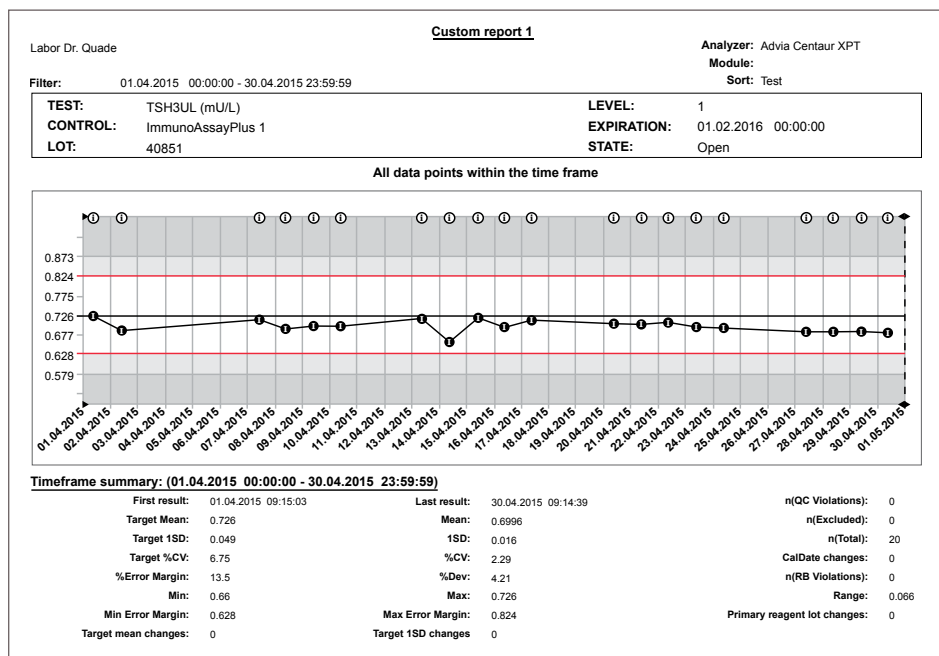


Figure 2. Report generated by the quality management software of the ADVIA Centaur XPT System. RiliBÄK rules (indicated by the red lines) are applied.

	ADVIA Centaur XPT System	ADVIA Centaur XP System	System Time Savings per Year	Operator Time Savings per Year
New test application	5 seconds	Technician >2 hours	2 hours minimum	
Loading of additional reagents	47 seconds	54 seconds		~1 hour
Monthly maintenance	Not needed	60 minutes	~12 hours	
Preparation for monthly maintenance	Not needed	5 minutes		~1 hour
Programming calibration	Automated	90 seconds		~8 hours
Daily maintenance	76:44 minutes	83:23 minutes	~28 hours within 253 working days	
Technician needed (troubleshooting)	1x/year	~5x/year		
Summary			~40 hours	~10 hours

Table 1. Aspects of daily routine work in our laboratory comparing the ADVIA Centaur XPT and ADVIA Centaur XP Systems.

“With the high-quality analytical performance of the new ADVIA Centaur XPT System we can easily meet our challenging external quality standards and internal requirements.”

Enhanced connectivity to Siemens middleware (CentralLink Data Management System) and LineMaster and the LIS

The ADVIA Centaur XPT System is able to communicate all system-generated information to the LineMaster. Intelligent routing to all ADVIA Centaur systems was smoothly directed by the LineMaster from the beginning, without any manual intervention. Easy data export (for example, quality management data) is also possible via USB and CD.

The new ADVIA Centaur XPT System has onboard quality control management that complies with current German Richtlinien Bundesärztekammer (RiliBÄK) quality management requirements*. (Figure 2) shows a screen shot of a custom report for TSH quality control (QC) level 1 in April 2015. All the required data, such as test date, assay name, QC expiration date, lot number, and RiliBÄK range, are available.

Workflow performance and achievements with the ADVIA Centaur XPT Immunoassay System

We analyzed the workflow performance of the ADVIA Centaur XPT Immunoassay System (with software version 1.02) from September 2014 through November 2015. With its technical and software improvements, the ADVIA Centaur XPT System has many advantages over the ADVIA Centaur XP System. We focused on the time an operator can save when working with the new system and if the technical improvements offer greater reliability (Table 1). The elimination of the monthly water reservoir cleaning procedure can save an operator approximately 13 hours annually. Calibrations are automatically requested and new assay applications can be scanned and loaded into the system automatically with the 2D barcode scanner, which saves approximately 28 hours per year. In summary, the laboratory can now operate the system an additional 40 hours annually because of the reduction in maintenance time.

*http://www.bundesaeztekammer.de/fileadmin/user_upload/downloads/Rili-BAEK-Laboratoriumsmedizin.pdf (german)
<http://www.degruyter.com/view/j/labm.2015.39.issue-1/labmed-2014-0046/labmed-2014-0046.xml> (english)

Method comparison and validation procedure for ADVIA Centaur XP Immunoassay vs. ADVIA Centaur XPT Immunoassay System

To ensure that the quality of patient care remains excellent, we evaluated the following assay parameters in our validation:

- Interassay CV (%) of internal QC
- Results of external QC (proficiency testing)
- Delta check in our laboratory information system (during medical validation)
- Risk assessment

To check the reproducibility of results, patient samples were analyzed in singlicate on both systems. Results generated on both systems were subjected to correlation analysis with the coefficient of determination. As examples regression plots and statistics for two core assays-TSH3-Ultra and free T3-show good correlation between the two systems (Figures 3 and 4). Additionally, results were evaluated using Passing-Bablok and Bland-Altman plots (not shown).

For the infectious-disease assays, we used 2 × 2 contingency tables. An example of such a table is Table 2, which, for the 8 positive and 12 negative test results, shows 100% correlation between the two systems.

German quality standards require that all three QC levels of a trilevel control be within the manufacturer’s range and also within the RiliBÄK range. Table 3 shows the intra- and interassay variation of measurements of QC materials for three core assays: TSH, Ferritin, and β-HCG. The intra-assay precision determinations involved analyzing QC materials for each assay 10 times on one day; the interassay precision assessment involved measuring QC materials for 3 consecutive days, with one measurement per day for each control level. All results were within the RiliBÄK-specified ranges, and all intra- and interassay precision results met RiliBÄK and Westgard rules and our internal requirements (Table 3).

We evaluated the proficiency of the three core assays by analyzing two different samples of predetermined values with each assay. All deviations, assessed both as CV for all ADVIA Centaur XP Systems and CV for the ADVIA Centaur XPT System only, were within the required ranges.

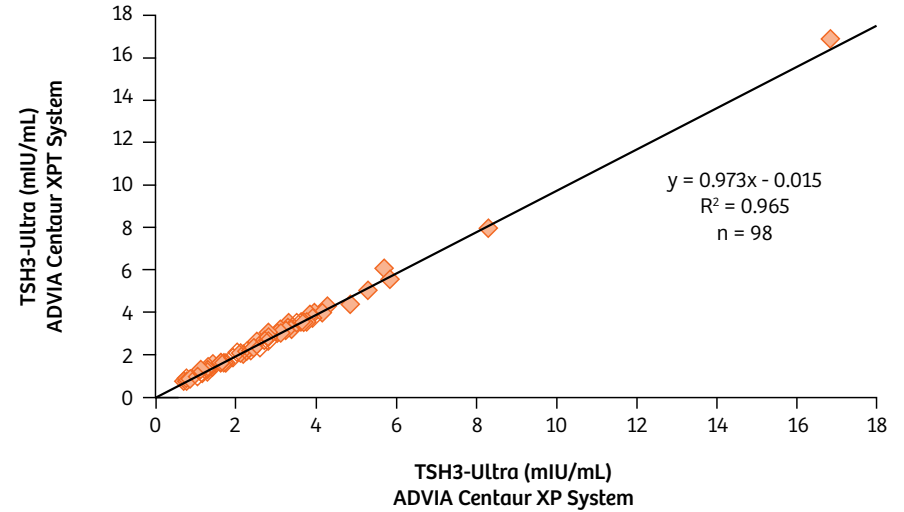


Figure 3. Regression line and statistics for TSH3-Ultra assay.

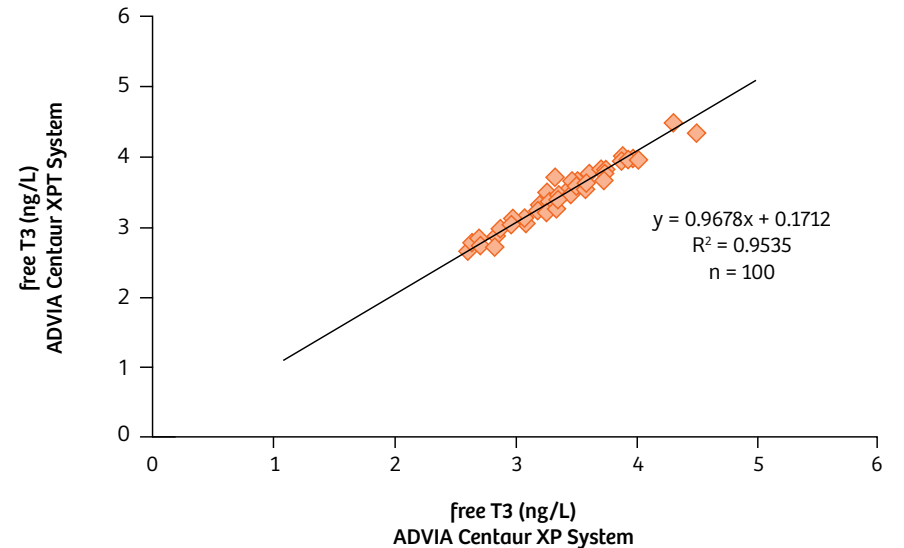


Figure 4. Regression line and statistics for free T3 assay

AD VIA Centaur XP	Positive	Negative	Total
AD VIA Centaur XPT			
Positive	8	-	8
Negative	-	12	12
Total	8	12	20

Table 2. 2 × 2 contingency table for anti-HCV assay.

Assays	QC Level	Intra-assay CV (%)	Interassay CV (%)	RiliBÄK Rules (acceptable deviation)	Westgard Rules (acceptable deviation)
TSH3-Ultra	Level 1: 0.513 - 0.938	2.36	4.97		
	Level 2: 3.11 - 7.75	1.22	2.07	13.5%	9%
	Level 3: 14.5 - 38.2	1.52	3.82		
Ferritin	Level 1: 16.5 - 27.5	3.17	1.21		
	Level 2: 142 - 236	1.24	5.17	13.5%	7.5%
	Level 3: 294 - 480	5.49	4.76		
β-HCG	Level 1: 3.86 - 9.30	3.51	7.3	14% >100 IU/L	
	Level 2: 19.3 - 34.1	2.43	5.44	17% ≤100 IU/L	
	Level 3: 289 - 423	1.16	3.68		

Table 3. Precision (intra-assay variation) and reliability (interassay variation) compared with corresponding RiliBÄK ranges and Westgard ranges. All results satisfied Westgard and RiliBÄK rules.

Assay	TSH (mIU/L)	Ferritin (µg/L)	β-HCG (IU/L)
Sample A Assigned Values	A: 18.8	A: 14.1	A: 119
Sample B Assigned Values	B: 8.93	B: 25.9	B: 621
AD VIA Centaur XP 1	A: 17.99 B: 8.65	A: 147.1 B: 23.9	
AD VIA Centaur XP 2	A: 18.77 B: 8.93	A: 141.3 B: 25.9	
AD VIA Centaur XP 3	A: 18.73 B: 8.84	A: 137.1 B: 24.8	A: 119.2 B: 613.5
AD VIA Centaur XPT	A: 19.23 B: 9.33	A: 144.4 B: 26.7	A: 124.6 B: 629.8
CV (all 3 AD VIA Centaur XP Systems) relative to assigned value	A: 2.76% B: 3.23%	A: 3.02% B: 4.85%	A: 3.13% B: 1.85%
CV (1 AD VIA Centaur XPT System only) relative to assigned value	A: 2.30% B: 4.49%	A: 2.41% B: 3.09%	A: 4.71% B: 1.42%
RiliBÄK (acceptable deviation in proficiency test)	24%	25%	30%

Table 4. Proficiency test results for two proficiency samples measured with each of three core assays run on multiple analyzers. All deviations were inside the RiliBÄK-acceptable range.

Further benefits for the operator

The new user software for the AD VIA Centaur XPT System is similar to that of the AD VIA Chemistry XPT System. Operators need only minimal training to work with both systems. For us, this is one of the most important improvements. The workstation (now Microsoft Windows-based) is physically integrated into the system and not separate as it was for the AD VIA Centaur XP System, which is more convenient for the user and saves space. The improved STAT sample list makes tracking urgent samples much easier and faster.

Our laboratory uses a system developed internally, called Computer-Aided Laboratory Management (CALM). This software monitors the entire workflow digitally (Laboratory 4.0). The CALM system features extensive Disaster Management[†]. The AD VIA Centaur XPT System, with its new software and platform to platform communication capabilities, can easily be integrated into the CALM system. We can therefore ensure better efficiency, more accurate and reproducible results, and proactive system-failure management.

Conclusion

The technical improvements in the new AD VIA Centaur XPT Immunoassay System lead to greater reliability and fewer maintenance interventions compared to the AD VIA Centaur XP System. It was easy and smooth to integrate the AD VIA Centaur XPT System into our established routine workflow. With the high-quality analytical performance of the AD VIA Centaur XPT System, we can easily meet our challenging external quality standards and internal requirements.

The new system offers many advantages for laboratories willing to take the next step towards even higher laboratory efficiency, greater accuracy of patient results, and faster result reporting. Ultimately, it can make the life of the laboratory technician easier and enhance the quality of patient care.

[†]Organization and management of resources and responsibilities for dealing with all aspects of laboratory emergencies, in particular:

- Preparedness: <http://www.ifrc.org/en/what-we-do/disaster-management/preparing-for-disaster/>
- Response: <http://www.ifrc.org/en/what-we-do/disaster-management/responding/>
- Recovery: <http://www.ifrc.org/en/what-we-do/disaster-management/from-crisis-to-recovery/>

These procedures should lessen the impact of disasters that affect your business.