Siemens Healthcare Diagnostics

3gAllergy®: Rising to Today’s Laboratory Productivity Challenges

Betsy Bononno, Director, User Experience and Design Validation
Siemens Healthcare Diagnostics  
3gAllergy™: Rising to Today’s Laboratory Productivity Challenges

Betsy Bononno, Director, User Experience and Design Validation

Siemens Healthcare Diagnostics answers the challenge of increasing laboratory productivity while reducing turnaround time (TAT) for all of a patient’s allergy results with the 3gAllergy Specific IgE Universal Kit and the flexible solutions provided by the Siemens family of systems.

Allergy diagnosis using automated and semiautomated systems in the clinical laboratory is notoriously time consuming and often considered noncritical testing for patient care. This view is often reflected in the limitations on the time and personnel resources allocated for allergy testing. A common testing paradigm may require running allergen panels (mixes of allergens) on patient samples on day one and, depending on results and time constraints, ordering additional specific allergen tests the following day. Rather than dedicate a system, a technician, and more than 8 hours to provide same-day reporting of results, laboratories often delay reflex testing on positive patient samples until the following day.

**Productivity study**

Siemens obtained allergy testing workflow data from several clinical laboratories in the U.S. and Europe to determine the impact of different testing platforms on result TAT and testing labor. Identical routine testing scenarios were studied in each of these laboratories. The assessment focused on both instrument and operator efficiency for several testing activities—preanalytical processes, routine patient testing, postanalytical tasks—and usable walkaway time. Productivity was measured by monitoring the time required to complete these activities along with calculating the walk-away time available to the operator during each activity.

The Siemens IMMULITE® 2000 immunoassay system demonstrated significant productivity gains over the IMMUNOCAP® 1000 in each of the activity phases described above. Specifically, the laboratory was able to complete more testing over a shorter period of time, requiring less operator intervention. When Siemens’ ADVIA® WorkCell® is used, it further increases productivity by expanding both the sample and reagent capacity, and allowing for continuous sample processing.

**Preanalytical processes**

Instrument preanalytical processes include tasks required to prepare the instrument for running samples, such as daily system maintenance and startup, assay adjustment/calibration, and quality control.
Rising to Today's Laboratory Productivity Challenges

Maintenance and startup

The study demonstrated that the IMMUNOCAP 1000's maintenance activities are significantly more labor intensive than those required on the IMMULITE 2000 system. The operator verifies that samples are received via the LIS list, then preloads the system by printing and reviewing the instrument checklist prior to replenishing consumables. By eliminating these activities on the IMMULITE 2000, the operator is able to complete maintenance on the IMMULITE 2000 system in one-third the time it takes on the IMMUNOCAP 1000, and to start calibration and quality control procedures considerably earlier.

Calibration and quality control

The time required to complete calibration and quality control processes was measured on both platforms. The study demonstrated that the IMMULITE 2000 system was able to complete these processes in significantly less time, thereby decreasing time to first result (TTFR). This difference can be attributed to additional priming activities required on the IMMUNOCAP 1000, which delay the launch of calibrator and control testing by 30 minutes. In addition, the IMMULITE 2000 system assay-processing time is approximately 40 minutes faster than that of the IMMUNOCAP 1000 (60 minutes vs. 100 minutes), resulting in approximately a 1-hour difference in result TAT. Moreover, the IMMUNOCAP 1000s observed were calibrated daily, whereas the IMMULITE 2000 system requires calibration only every 2 weeks.

The combined effect of the additional maintenance and calibration times along with assay TAT differences creates a significant delay before the lab can start processing patient samples. The IMMUNOCAP 1000 requires 3.5 hours to complete these activities, whereas the IMMULITE 2000 system is ready to start processing samples in less than half the time. These instrument features impact both operator walk-away time and the daily testing capabilities of the laboratory.

<table>
<thead>
<tr>
<th>Time to Complete Maintenance Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMMULITE 2000</td>
</tr>
<tr>
<td>23 minutes</td>
</tr>
</tbody>
</table>

Time to First Result

<table>
<thead>
<tr>
<th>Time to First Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMMULITE 2000</td>
</tr>
<tr>
<td>82 minutes</td>
</tr>
</tbody>
</table>

Processing patient samples

Allergy testing typically includes an initial patient screen using one or more allergen panels (e.g., tree panels, food panels, inhalant panels, etc.) to determine whether the patient is positive for a family of different substances. If the results from this initial screen are positive, the sample is typically retested to determine the specific allergen(s) causing the allergic reaction. This testing paradigm can be very time and labor intensive since it requires a second test to be performed following the results from the initial test.

In this testing scenario, the IMMULITE 2000 system completed all patient screening and specific allergen retesting within an 8-hour shift; the IMMUNOCAP 1000 required part of an additional day to complete the same workload. The TAT of the IMMULITE 2000 system was possible because of the reduced time spent on preanalytical activities, which provided sufficient time for same-day reflex testing on positive patient samples.

Currently, positive allergy samples can be configured to autoreflex using an LIS. In a future version of IMMULITE 2000/2500 software, this capability will be configurable on the instrument without the need for an LIS. Such flexibility will enable the instrument to automatically launch repeat tests more quickly and without operator intervention. As a result, the system will be able to provide same-day results for both allergy screening and specific allergen testing.

In contrast, samples that require retesting on the IMMUNOCAP 1000 cannot be completed within an 8-hour window and are held over to the following day, preventing same-day result reporting to customers. In addition, processing these samples requires another calibration cycle and significant operator intervention to find and reload the samples for secondary analysis.

Evaluating the data on a continuous time scale, a patient testing volume of 64 samples generating 334 tests required approximately 11.5 hours across two days (or shifts) for completion on an IMMUNOCAP 1000 vs. 7.5 hours on one day using the IMMULITE 2000 system.

The additional hours needed to complete all test results using the IMMUNOCAP 1000 in these studies were a result of holding positive patient results for next day reflex testing. Repeating preanalytical procedures the following day added another 209 minutes of preanalytical time, along with the time needed to produce the final reflex test result.
Immunoassay WorkCell

The Siemens family of systems provides solutions that grow along with a laboratory’s needs to accommodate larger volumes of allergy testing. The foregoing example presented a medium to large daily testing volume for allergy that was readily handled by a stand-alone IMMULITE 2000 system. Larger volumes with a more diversified allergy test menu are accommodated with the Siemens Immunoassay (IA) WorkCell®. This system integrates two IMMULITE 2000 systems, using a Sample Management System (SMS) as a single interface for managing samples and results. By adding additional analytical capacity and a common sample-handling unit, the laboratory can more than double the productivity potential. In addition, the SMS provides continuous sample loading capabilities with an increased storage capacity for 200 samples, providing additional user walk-away time.

To demonstrate the productivity increase realized with the IA WorkCell, a study was performed doubling the testing requirements described in the previous scenario. From start to finish, the workload of 128 samples, 608 patient tests, required 21 hours using the IMMUNOCAP 1000, compared to 9 hours and 14 minutes using the IA WorkCell. The IA WorkCell required only 40 percent of the time needed by the IMMUNOCAP 1000 to complete identical test/assay mixes.

Summary

Today’s laboratories face productivity challenges when performing allergy testing because of time and resource limitations. Productivity evaluations of both the Siemens IMMULITE 2000 system and the IMMUNOCAP 1000 demonstrated differences in the time required to perform maintenance, calibration, all patient test results, and end-of-day procedures within a 24-hour period.

The IMMULITE 2000 system running Siemens’ 3gAllergy Specific IgE Universal Kit demonstrated significant productivity gains over the IMMUNOCAP 1000 in terms of pre- and postanalytical activities, patient testing protocols, and the usable walk-away time during each activity. On the basis of volume of tests and work hours allocated for completion of test results, either the single IMMULITE 2000 system or the IA WorkCell provides significant productivity gains over the IMMUNOCAP 1000 system.

Additional system benefits of the IA WorkCell include the ability to add more allergens and load more patient samples—200 samples, which is more than double the system capability of stand-alone systems. Samples can remain onboard for seamless autoreflexing of positive patient samples, and an operator can load samples on the fly, eliminating the need for a batch-testing environment. These advantages of the IMMULITE 2000 system and IA WorkCell allow the laboratory to offer same-day allergy testing results. With Siemens’ flexible solutions, the laboratory can increase its productivity and enhance its service to the requesting physician for more timely patient care.