Clinical Evaluation of the Dynacon Innova Automated Specimen Processor in a High Volume Clinical Laboratory

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Revised Abstract

Clinical evaluation of the Becton Dickinson Innova (formerly Dynacon Innova), an automated specimen processor, was conducted in a large regional laboratory to evaluate accuracy of plating, cross contamination, reliability and throughput. The Innova allows for the complete automation of the "front-end" processing of liquid samples in the clinical laboratory. Specimen types were plated using the Innova and current in-house methods, including both automated and semi-automated plating. Specimens plated consisted of 636 urine Boric Acid tubes (Becton Dickinson), 149 throats and 90 skin and soft tissue swabs submitted in eSwab transport (Copan Diagnostics), 73 stools submitted in C&S Transport (Meridian Diagnostics), and 129 Group B Strep broth tubes (Becton Dickinson). The Innova can process varied types of specimens without manual intervention or changing of components, thus minimizing the operator time.
Overall correlation between the current in-house methods and the Innova was 97.4%. The absence of cross-contamination was demonstrated by alternating 25 positive urine boric acid tubes with 25 tubes filled with sterile water. Lastly, instrument throughput was evaluated using various media plate combinations and streak patterns. Innova processed 120-138 whole plates/hr and 92 urine bi-plates/hr.
In conclusion, the quality and consistency of plating by the Innova is equivalent or superior to our current plating methods. There are many other benefits to employing automation for specimen processing, including decreased labor requirements and greater reproducibility of results. Throughput is faster than current in house methods and appears to be equivalent to other automation platforms on the market. Finally, the Innova is ideal for a high volume laboratory due to its large capacity and long walk-away time but also suitable for small to medium volume laboratories due to its versatility in processing a wide variety of specimen types at once with minimal operator intervention required.

Materials & Methods

To assess the performance of the Innova plating instrument specimens were plated using in house methods which included the Isoplater (Vista Technology Inc.) for throats, miscellaneous and stool specimens and the Innoculab (BD) for urine and GBS Todd Hewitt broth specimens. The Isoplater is a semi-automated instrument in which the specimen much be initially inoculated onto the media plate. Plates are then loaded onto the instrument for streaking. The Innoculab is a fully automated instrument for plating of liquid specimens. A 30 µl loop was used to inoculate all the specimens on the Innova except for the urine cultures in which a 1µ loop was used.

Accuracy

To assess comparison between the various in house methods and the Innova specimens, the following samples were plated:

- Urine: 636 (43 specimens were removed from data analysis due to incomplete data). A total of 593 were compared.
- Throat [eSwab]: 145
- Group B Strep Broths [GBS]: 129
- Stool: 70
- Non-sterile Miscellaneous [eSwab]: 90

The study was blinded in that the results of the samples performed by the reference method and the Innova were linked back together by an individual who did not participate in the initial processing or work up of the samples. This portion of the study was completed over several days of testing.

Cross Contamination/Carryover

Known positive samples with high bacterial concentration were alternated with containers of sterile water over two separate runs. The results were assessed for the presence of bacterial contamination on sterile water sample plates.

Reliability/Reproducibility

Reproducibility testing was performed by running the same specimen in duplicate on the Innova and in singlet on the reference method.

Throughput

Throughput was determined by running an established protocol and determining the average time per specimen, number of specimens per hour, and the number of plates inoculated per hour.

Figure 1. Becton Dickinson Innova

Results

Table 1. Correlation Summary

Source	Total tested	Discrepants	% Correlation
Urine	593	17	97.1%
Throat [eSwab]	145	2	98.6%
GBS broth	129	3	97.7%
Stool	70	0	100.0%
Miscellaneous [eSwab]	79	4	94.9%
Total	1016	26	97.4%

- Overall correlation between in house methods and Innova was 97.4%.
- Urine - Of the 17 discrepant specimens 14/17 were thought to be clinically significant due to either organism quantitation or identification of the pathogen.
- Throat [eSwab] - Of the 2 discrepant specimens, Group A Strep was isolated from plates inoculated using the Innova but not from those plated using the Isoplater.
- GBS - Of the 3 discrepant specimens, 2 were negative for GBS when plated using the Isoplater but had no growth on the Innova plates (absence of normal flora on Blood Agar). It is unclear if there was a plating issue resulting in the Innova plates being uninoculated. One specimen was positive for GBS when plated using the Innova but negative when plated using the Isoplater.
- Miscellaneous [eSwab] - Of the 4 discrepant specimens 2 resulted in no growth when plated on the Innova and whereas there was growth on the specimens plated using the Isoplater. Two additional specimens did not agree with identification of the organism.

Figure 2a

Figure 2b

Figure 2 a & b. (a) View internally of BD Innova de-capping system which removes various size specimen transport caps during the media inoculation step. (b) View internally of the BD Innova 30 µl loop which inoculates the specimen onto the plated media

Table 2. Reproducibility Summary

Source	Total tested	Discrepants	% Correlation
Urine	273	1	99.6%
Throat [eSwab]	100	0	100.0%
GBS broth	95	1	98.9%
Total	468	2	99.6%

- Urine – a GBS failed to be detected on plate #2.
- GBS – a GBS was isolated on plate #2. (Note: the GBS was not recovered from the specimen plated using the Isoplater).

Table 3. Throughput

Specimen/Streak Pattern	# Plates per Protocol	Av. Time per Specimen (secs)	# Specimen/Hr	# Plates/Hr
Urine/zigzag	1	39	92	92
GBS/4-quad.	1	30	120	120
eSwab/4-quad	3	90	40	120
Max speed/zigzag	1	26	138	138

Conclusions

- Based on this evaluation of a prototype Innova instrument the overall agreement was 97.4% compared to in house plating methods.
- Reproducibility had a 99.6% agreement.
- The Innova has the ability to plate between 736 to 1104 specimens in an eight hour shift with continuous feed of specimens and plates.
- The Innova has the potential to decrease labor costs, mitigate workplace or ergonomic injury due to manual plating, and improve consistency/quality in streaking of the specimen.

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