

IMPACT OF CONVERTING FROM CONVENTIONAL TUBE CULTURES TO SHELL VIALS: A COMMUNITY HOSPITAL LABORATORY'S EXPERIENCE

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IMPACT OF CONVERTING FROM CONVENTIONAL TUBE CULTURES TO SHELL VIALS: A COMMUNITY HOSPITAL LABORATORY'S EXPERIENCE.

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Objective: Improve and streamline virology services at a community hospital by reducing workload, reporting negative and positive specimens more quickly to aid user physicians in patient care. We looked at methods generated toward reclaiming the virology section to take advantage of more modern methods including co-cultured cells including engineered cells, and rapid staining to allow for more rapid reporting. Our prior experience in traditional virology lead to a reliance on multiple tubes, lengthy trainings to bring new technologists to a comfort level to accurately read and interpret cytopathic effect, and reliance on a number of protocols to accomplish various culture tasks.

Methods: We compared traditional tube and DFA or IFA staining of CPE positive specimens to shell vial methods using ELVIS, R Mix, E Mix and H and V Mix. (Diagnostic Hybrids, Inc) for time to culture and time to report. Testing was performed both on proficiency or training panels. CAP linkways said patient specimens received throughout the year from inpatients and outpatient populations. We also looked at the incidence of various viruses before and after adopting the shell vial methods. Results: There was a dramatic decrease in turn around using the shell vial method. Most positive specimens could be detected within 1-5 days.

Method	Annual Volume	Time From Test	Time to Report	Cost	Comments
Respiratory	200-300 (100% to 100%)	14 days	72 hours or less	1.50 (Mk Mix) (reporter) 2.00 (Mk Mix) (reporter) 2.00 (Mk Mix) (reporter)	72 hours or less
Enterovirus	70	21 (100%)	72 hours or less	2.00 (Mk Mix) (reporter) 2.00 (Mk Mix) (reporter) 2.00 (Mk Mix) (reporter)	72 hours or less
CMV	72	48 (75%) 5 days to 97 (100%)	14 (80%) 21 (100%)	1.50 (Mk Mix) (reporter) 2.00 (Mk Mix) (reporter) 2.00 (Mk Mix) (reporter)	72 hours or less
VZV	72	48 (75%) 5 days to 97 (100%)	14 (80%) 21 (100%)	1.50 (Mk Mix) (reporter) 2.00 (Mk Mix) (reporter) 2.00 (Mk Mix) (reporter)	72 hours or less

Conclusions: We were able to significantly reduce turn around time as well as reduce the number of items used. Additionally, we were able to decrease the labor required to process and maintain tube cell cultures, including extensive quality control of cell lines.

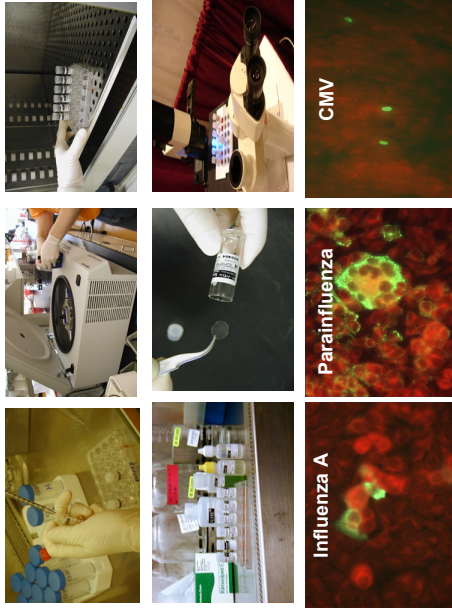
Introduction:

Borgess Medical Center is a 440-bed community hospital which services a 4 county area in southwestern Michigan. The Virology laboratory was established in 1988 using traditional tube culture techniques and adding enhanced shell vial technology as it became available. We successfully evaluated the ELVIS® product (Diagnostic Hybrids, Inc.®) in the fall of 1990 and subsequently converted to that methodology for herpes simplex cultures. As DHI® introduced new product lines, we performed validation/evaluation studies as follows: H&V mix® (Varicella zoster) and R-mix® (respiratory viruses) in 2000, E-mix® (enteroviruses) in 2001/2002, and Mv-1Lu with Turbo Treat® (CMV) in 2002/2003. Results of these evaluations are shown below. We completed a total conversion from conventional shell vial/tube culture methodology in our laboratory to all DHI® co-cultivated or engineered cells after the final CMV culture evaluation. The cost of the DHI vials was higher than our traditional tube or shell vial on an individual basis, but after the cost of passing to new tubes and the total number of tubes was evaluated, there was no additional reagent cost involved and in some cases (enterovirus and respiratory virus cultures), there was a significant reduction in reagent costs. Turnaround time was dramatically decreased and conversion from our conventional methodology resulted in significant labor savings.

Methods

- Conventional Tube Protocol:** Former internal procedures at Borgess MC:
 - Required daily examination for CPE
 - Required refeeding of tube every 72 hours
 - Required passage of culture to new tube every 7 days; greater chance for contamination, doubles cell costs
 - Required technologists to scrape tubes and make staining preparations
 - Required extensive quality control of each cell line
- New Shell Vial Protocols following DHI recommended labeling data:**
 - Require no daily CPE reading, inoculate, incubate and stain
 - Only one feeding at time of set up
 - Requires no passage to other shell vials; additionally contamination is reduced due to shorter culture incubation time
 - Staining is performed in most instances on undisturbed cells allowing better visualization of cells
 - Quality control is reduced to observing negative cells and staining controls

Simple Standardized Processing and Inoculation for all Specimen Types



ELVIS FOR HSV

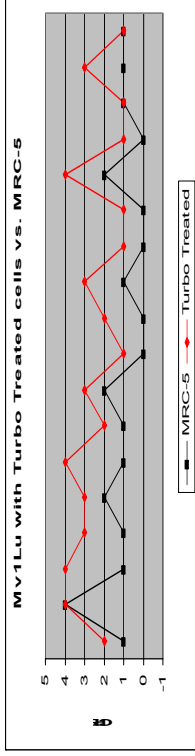
- 118 patient specimens evaluated with 27 positive for HSV.
- 100% agreement with conventional shell vial/tube culture methodology.
- ELVIS® vials held 18 hours; conventional culture 5 days.
- Total turn around to final results decreased from 5 days to 18 hours.
- Costs decreased by slightly more than \$10.05 per specimen including tech time.
- 800 samples tested annually.
- Total savings annually including expendables and technologist time, \$8,208

Enterovirus and E Mix Testing

- 98 patient specimens evaluated with 20 positive for enterovirus.
- 100% agreement between E-Mix shell vials and conventional culture.
- 19 of 20 patient isolates recovered at 20 hours; one at 5 days on E-Mix. E-Mix vials held total of 5 days.
- Average time to detection with conventional shell vial/tubes was 8 days with final results reported after 28 days.
- Total turnaround time to final result decreased from 28 to 5 days.
- Special Note: During evaluation, CPE was observed at 13 days in the A 549 tube culture, E-Mix was negative. The isolate was identified as an adenovirus. Upon implementation of E-Mix, we add adenovirus to our staining panel at 5 days.
- Total savings per specimen including technologist time and expendables, \$11.62
- Annual Savings: \$2,033

CMV Testing

- 106 patient specimens were evaluated with 18 positive for CMV.
- 18 positive CMV cultures using Mv-1Lu with Turbo Treat® and 14 positive with conventional MRC-5 shell vials.
- 100% agreement in recovery between Mv-1Lu vials with Turbo Treat® and conventional shell vials/tubes.
- Mv-1Lu vials were held for 72 hrs; conventional tubes held for 28 days.
- Total turn around time decreased from 28 days to 72 hrs.
- Post evaluation, we implemented use of 2 Mv-1Lu vials with Turbo Treat® stained at 20 and 72 hours. We discontinued using conventional shell vials and tube cultures.
- Mv-1Lu improved recovery and enhanced replication of CMV. A remarkable difference was observed in the level of CPE in Mv1Lu Shell vials vs. MRC-5
- Savings per specimen including technologist time and expendables, \$8.88
- Annual savings: \$710

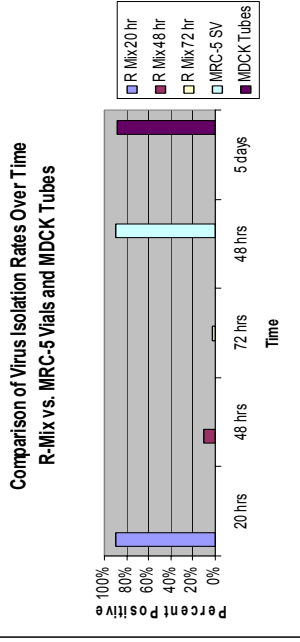


H and V Mix Cultures for VZV

- 74 patient specimens tested with 19 positive for VZV
- All 19 positives isolated in H and V Mix vials
- 18 positives recovered in shell vials/tubes using conventional method
- 15 VZV isolates were recovered at 48 hours with H and V Mix, and additional 4 vials were positive by staining at 5 days
- Average time to detection with conventional vials and tubes was 6 days
- Conventional staining was at 48 hours, 5 days and 21 days
- Turn around decreased from 21 days to 5 days for a final report
- Savings per specimen including technologist time and expendables: \$2.79
- Annual Revenue Savings: \$194.00

CONCLUSIONS

Conversion from conventional culture to DHI shell vial methods has dramatically reduced reporting turn around time, formerly 5-28 days, now 20 hours to 5 days, improved recovery rates of respiratory viruses and training of technologists is comparable. Reduction of initial reporting time of respiratory viral cultures using R Mix cells reduced time to detection from 14 days to 28-40 hours and has positively impacted our hospital infection control process and patient bed management during the influenza season. Technologist productivity has been significantly impacted, reducing technologist time from 2 to 24 minutes per sample. Annual savings for all methods totaled approximately \$36,393.



- 133 specimens evaluated with 108 positive for a respiratory virus.
- All 108 respiratory viruses recovered with R Mix vial; 97 using conventional MRC-5 shell vials and tube media. During the evaluation, 3 R Mix vials, stained at 20, 48 and 72 hours were compared to conventional cultures.
- R Mix cultures are held a total of 72 hours; conventional cultures 14 days.
- Discrepant results:
- Enhanced MRC-5 (48 hrs) vs. R Mix (48 hrs):
- 3 specimens failed to grow in MRC-5 vials but were recovered in R-Mix.
- 1 specimen was positive in the MRC-5 vials and negative in R Mix vial.

- Current protocol includes 2 R Mix vials, stained at 20 and 72 hours.
- Total turn around time decreased from 14 days to 72 hrs; with 90 % of positives reported at 20 hrs.
- Technologist time minutes saved per specimen 15 minutes
- Savings per culture \$15.76 including technologist time and expendables
- Total Annual Savings \$25,248