

Case Study: Comparison of Cost and Efficacy of Complete Cell Culture Media vs. Home-Brew Media

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Objective

In order to reduce the cost and complexities involved in purchasing GMP standardized media, Hospitals and various research facilities have created home-brew media by assembling various components to make a complete cell culture medium. However, compliance-related issues, labor considerations, the ability to completely replicate each brew batch, and issues related to acquiring raw materials, have prompted various institutions to consider challenging the perceived advantages of home-brew media over its alternatives.

This study, performed by Dr. Brandon Shaw, compares the efficacy of a complete cell culture medium from a GMP manufacturer with the laboratory's homebrew medium, as well as the evaluation and analysis of cost associated with each option.



Methodology

The Laboratory's Home-Brew vs. Complete Cell Culture Medium Efficacy Study

Bone marrow aspirate samples were received and 24-hour cultures were initiated utilizing the laboratory's home-brew medium, CHANG BMC, and CHANG Marrow. All samples were subjected to the same harvesting, dropping, and banding methods as described in current protocols. Once completed, slides were scanned utilizing the Cytovision GSL-120 and the number of metaphases captured by the instrument was recorded. Slides were then reviewed at the microscope using a 20x objective and the number of nuclei within five separate fields in random regions of the slide were counted.

These data were utilized to extrapolate the total number of nuclei based on the area of the slide. Based on these numbers, the mitotic index of the slide was calculated for each medium type. Similar experiments were conducted utilizing the laboratory's home-brew medium, CHANG Marrow, and CHANG MF to determine the efficacy of the media in DSP/IL2 stimulated cultures. CHANG MF was also evaluated against the current medium in peripheral blood cultures with FUHR and PHA, respectively. Statistical analysis was performed utilizing the mitotic index from the slides generated under the above conditions via a T-test.

Home-brew vs. Complete Cell Culture Medium Cost Analysis Study

For this comparison study, over 2,300 peripheral blood and bone marrow cultures each were set up using both a complete cell culture medium as the control and a home-brew cell culture medium as the test subject. Each culture was set up using a complete CHANG cell culture medium (CHANG Medium MF) and a home-brew cell culture medium consisting of a basal medium (RPMI), fetal bovine serum (FBS), L-Glutamine, and an antibiotic for peripheral blood and bone marrow cultures. The total savings resulting from using complete cell culture medium vs. using home-brew cell culture medium was greater than 10%, valued at approximately \$630 USD.

Over 2,450 bone marrow cultures were set up using both the laboratories' home-brew cell culture medium and a complete CHANG cell culture medium. The home-brew cell culture medium cocktail consisted of RPMI and a selection of various growth factors including Giant Cell Tumor Conditioned Medium (GCT), added to the final mixture depending on the patient's oncology diagnosis. The complete CHANG cell culture media samples used either CHANG Medium MF with the same growth factors as the home-brew medium, without GCT, or they used CHANG Marrow by itself, which contains GCT. The total savings resulting from using complete cell culture medium vs. using home-brew cell culture medium was also greater than 10%, or approximately \$3,670 USD.

Results

Ability of CHANG Marrow/CHANG BMC to support growth in the replacement of 24-hour GCT cultures

The study showed no statistically significant difference in the mitotic index of the three media. Based on this, the decision was made to begin utilizing CHANG Marrow in lieu of 24-hour GCT cultures.

Ability of CHANG Marrow/CHANG MF with DSP/IL2 to support growth in replacement of 72-hour DSP/IL2 cultures

The study showed a statistically significant increase in the mitotic index of CHANG Marrow with DSP/IL2 in comparison to CHANG MF with DSP/IL2 and current 72-hour DSP/IL2 cultures. There was no statistically significant difference between CHANG MF and the current home-brew medium. The decision was made to utilize CHANG MF with DSP/IL2 as the medium content of CHANG MF is the most similar to the medium used in current practices; however, the abnormal capture rate of CHANG marrow with DSP/IL2 in comparison to CHANG MF with DSSP/IL2 may be investigated at a later date.

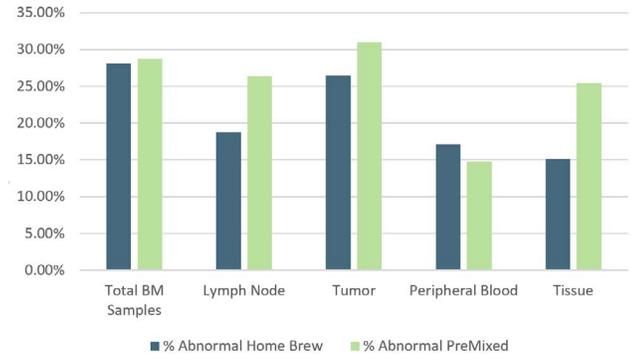
Ability of CHANG MF with FUDR or PHA to support growth in the replacement of current media with FUDR or PHA

The study showed no statistically significant difference in the mitotic index of the CHANG MF with PHA and the current home-brew medium with PHA. The study also did not show a statically significant increase in the mitotic index of CHANG MF with FUDR in comparison to the current home-brew medium with FUDR. Based on this data the decision was made to utilize CHANG MF with FUDR or PHA instead of the current home-brew medium.

Estimated cost savings: Based on reduced time required to use complete cell culture medium vs home-brew medium

Assembling home-brew cell culture medium requires more time for the technologist to assemble and mix the components properly, and to evaluate the performance compared to using GMP manufactured complete cell culture media. The total amount of time saved performing the two studies listed above using the complete cell culture medium vs. using the home-brew cell culture medium was approximately 58 hours, which resulted in cost savings of greater than \$1,800 USD.

CHANG Complete Cell Culture Medium Performance vs. Home-brew



Summary

The validation showed either no statically significant difference between the medium tested or a slight increase in favor of the complete cell culture medium. Additionally, the utilization of standardized media in the laboratory will decrease costs associated with the procurement and assembly of the home-brew, reduce the variability of the medium, and increase consistency across all culture types. Due to the small numbers and decreased sample size of tumor, lymph node, and tissue specimens in the laboratory, these sample types were not included in the study. However, the current practices for these samples are similar to the tested cultures and the use of the new media types is not predicted to have a negative impact on them. Based on these findings, the decision to switch to CHANG Marrow and CHANG MF with FUDR or PHA for bone marrow aspirates, peripheral blood, tumor, lymph node, and tissue specimens was carried out, providing better performance for less cost.

The detection of genetic abnormalities is of paramount concern when culturing cells from bone marrow and other tissue samples to provide essential information regarding chromosomal changes for patients diagnosed with cancer. The bone marrow, lymph node, tumor, and other tissue samples that were grown in a complete cell culture medium showed a higher percentage of abnormalities were detected than in cultures that were grown using home-brew media. This improved ability to detect chromosomal abnormalities using complete cell culture media demonstrated to the laboratory that moving away from preparing home-brew media was the recommended choice.