

PURPOSE

A high throughput automated system was developed to determine pH of culture media using a pH module equipped with an external flow cell. A custom septum piercing, vented needle was developed to accommodate the shape and size of the customer sample vials. For this application, both accurate and precise pH measurements were required. The data presented in this document was collected by a customer as a part of their validation process and was provided for use with their consent.

METHOD

The system is comprised of a sample processor with capacity for 110 culture media vials, a pH module, and one dosing device with 50 mL buret. Specially made vented needles were developed to accommodate the size and shape of the customer vials. For electrode calibrations and pH measurements, the needle is lowered and pierces the septum seal of the vial. The dosing unit and buret system extracts the appropriate amount of sample into the pH flow through cell where the pH measurement takes place. After each measurement, the dosing unit then rinses the needle and tubing in preparation for the next measurement. For this study, three different systems were evaluated over two days for accuracy and precision.

EQUIPMENT

- Sample processor
- pH module
- pH flow through cell
- External needle rinse
- tiamo™ titration software

RESULTS

Electrode Calibration

Each electrode was calibrated using Metrohm pH 4, 7 and 9 buffers. Two different buffers (pH 5 and pH 8) by a second manufacturer were used as check standards to determine method accuracy and precision. The results of those measurements can be found in the table and figures below. Buffer checks were performed after calibrations and intermittently after sample vials were analyzed.

Buffer 5 was determined to be pH 5.01 ± 0.01 and buffer 8 was 8.05 ± 0.005. Measurements at both pH units resulted in precision of less than 0.2% relative standard deviation.

Culture Media pH Measurements

Product precision was determined by taking duplicate measurements on 10 sample vials using three systems on two separate days. The results shown in the table for each vial is the mean of the duplicate measurements.

The acceptable precision for this customer was ≤ 0.05 pH units from day to day. All three instruments met this criteria with standard deviations of less than 0.02 pH units.

	System 1		System 2		System 3	
Slope (%)	98.8		98.7		98.6	
	pH 5.00	pH 8.00	pH 5.00	pH 8.00	pH 5.00	pH 8.00
Buffer Check 1	5.02	8.04	5.00	8.04	5.00	8.05
Buffer Check 2	5.01	8.04	5.00	8.04	5.02	8.05
Buffer Check 3	5.02	8.04	5.00	8.05	5.01	8.05
Buffer Check 4	5.01	8.05	5.01	8.04	5.00	8.05
Buffer Check 5	5.02	8.04	5.02	8.05	5.02	8.05
Buffer Check 6	5.02	8.04	5.01	8.05	5.03	8.05
Buffer Check 7	5.02	8.04	5.01	8.05	5.00	8.04
Buffer Check 8	5.02	8.04	5.01	8.05	5.01	8.04
Average	5.02	8.04	5.01	8.05	5.01	8.05
Standard Deviation	0.005	0.004	0.007	0.005	0.011	0.005

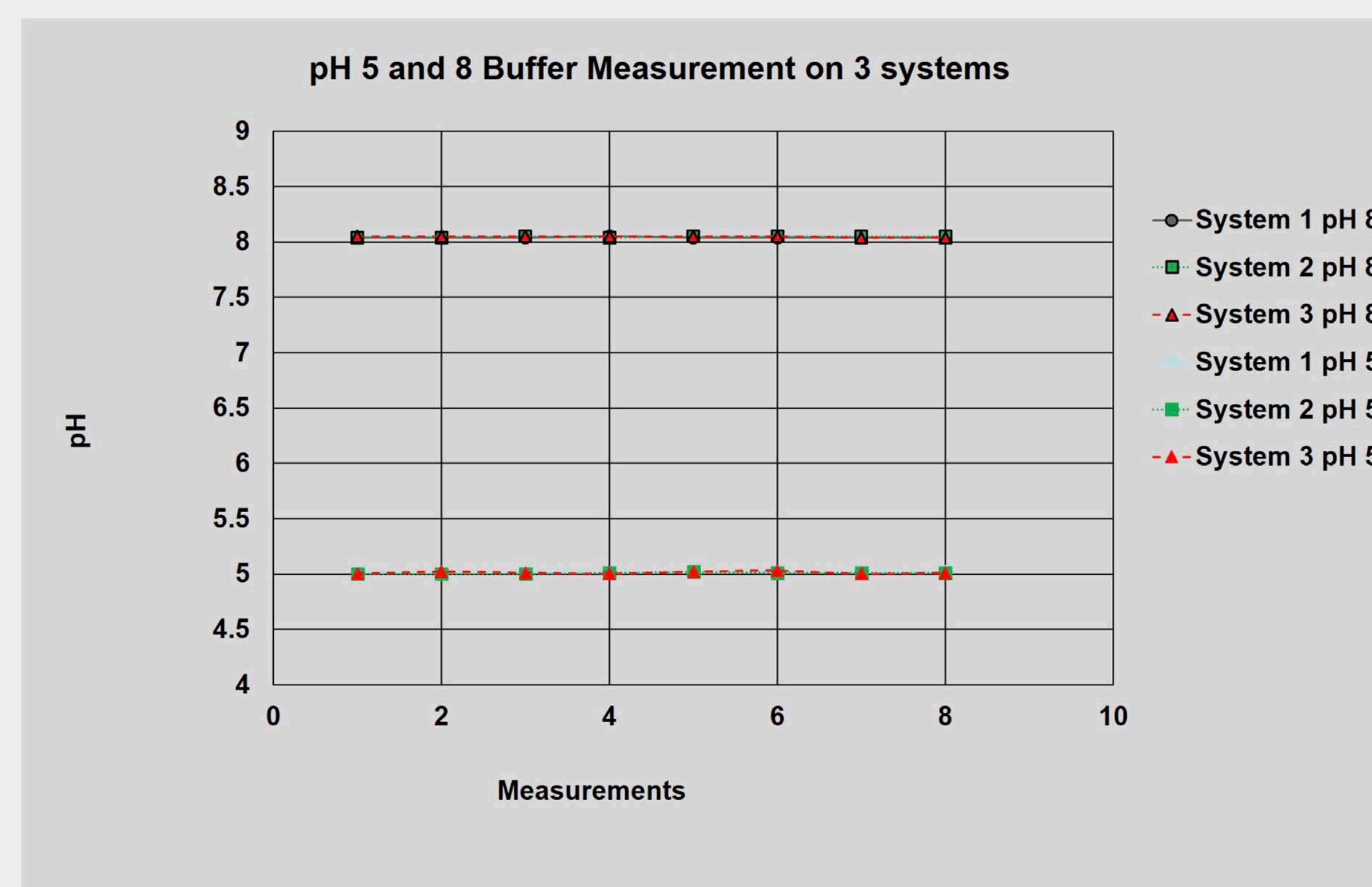


Figure 1. Eight replicates of pH 5 buffer measurements on 3 systems

Sample	System 1 Day 1	System 1 Day 2	System 2 Day 1	System 2 Day 2	System 3 Day 1	System 3 Day 2
Vial 1	7.214	7.200	7.187	7.194	7.212	7.184
Vial 2	7.212	7.228	7.217	7.214	7.211	7.195
Vial 3	7.196	7.203	7.193	7.216	7.202	7.161
Vial 4	7.180	7.221	7.195	7.201	7.188	7.193
Vial 5	7.243	7.194	7.200	7.207	7.201	7.165
Vial 6	7.214	7.204	7.202	7.223	7.204	7.189
Vial 7	7.203	7.194	7.212	7.217	7.194	7.176
Vial 8	7.189	7.204	7.206	7.210	7.214	7.182
Vial 9	7.186	7.207	7.183	7.204	7.192	7.192
Vial 10	7.206	7.218	7.192	7.206	7.192	7.206
Average	7.204	7.207	7.199	7.209	7.201	7.184
Standard Deviation	0.018	0.011	0.011	0.009	0.009	0.014

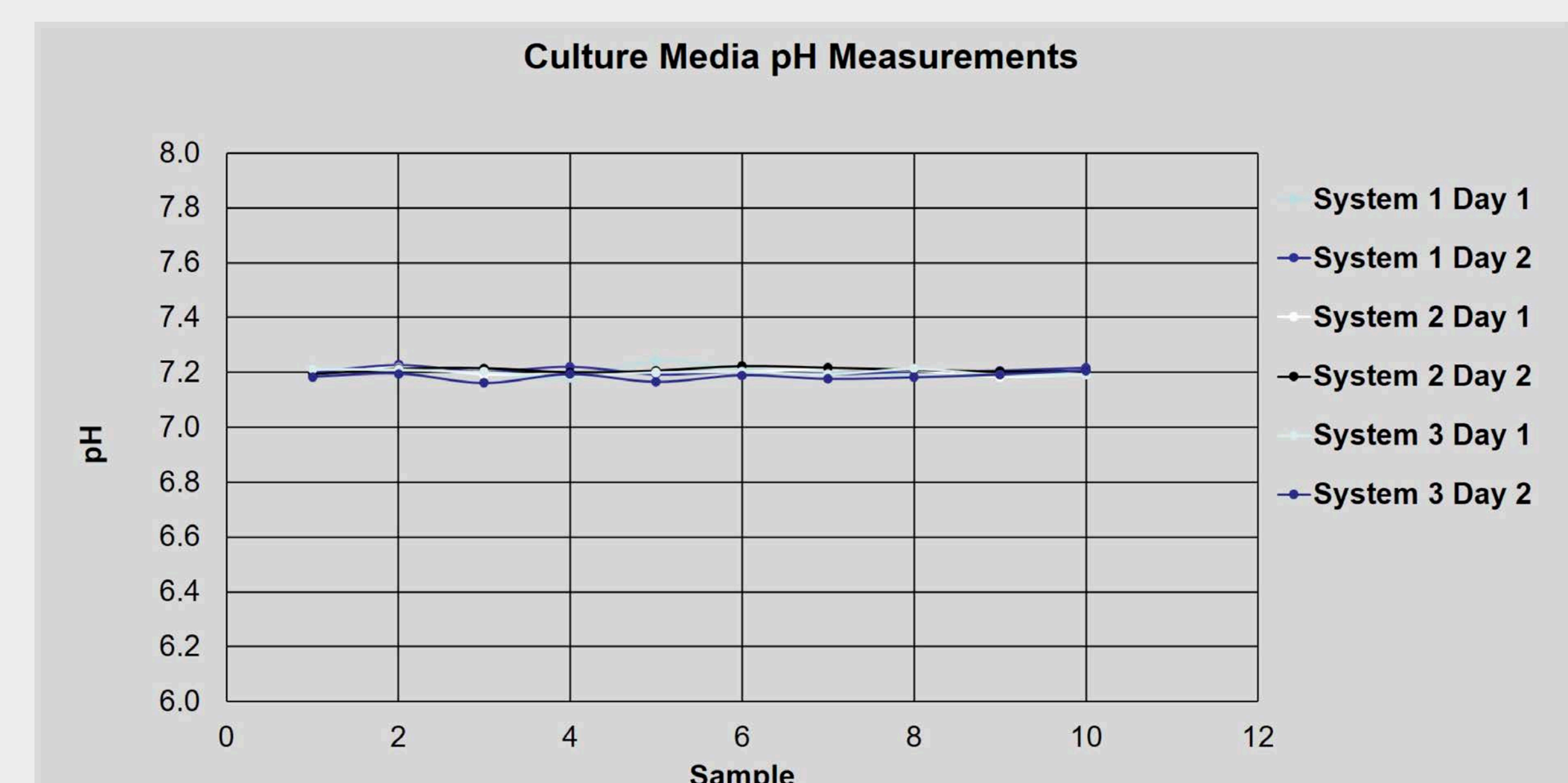
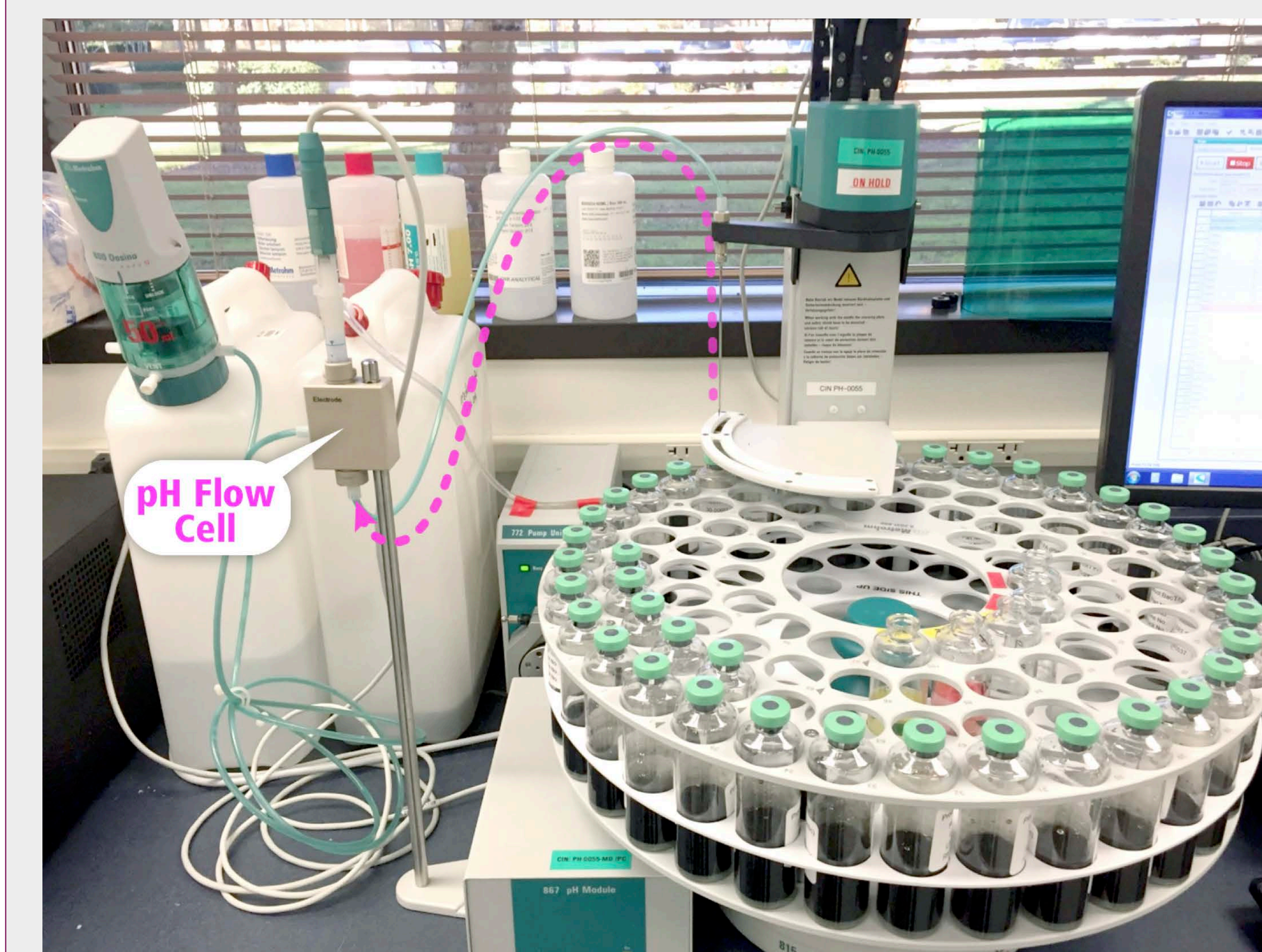


Figure 2. Culture media pH measurements using 3 systems on 2 days

INSTRUMENT



Sample Processor with pH Module, pH flow through cell and external needle rinse.

CONCLUSION

The designed automated system accurately and precisely determined pH values using a sample processor and pH flow through cell equipped with a custom venting needle and rinse system.