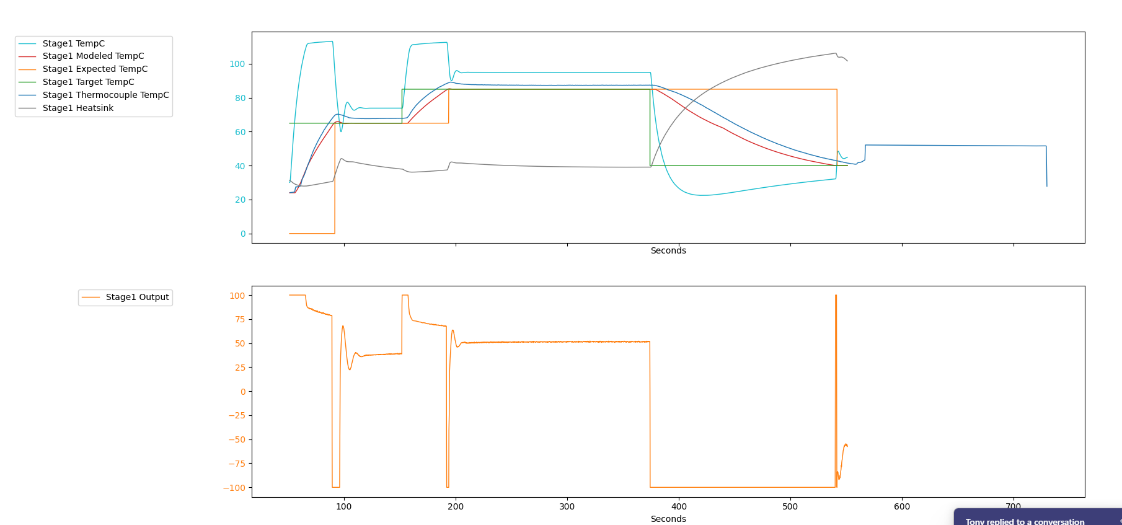
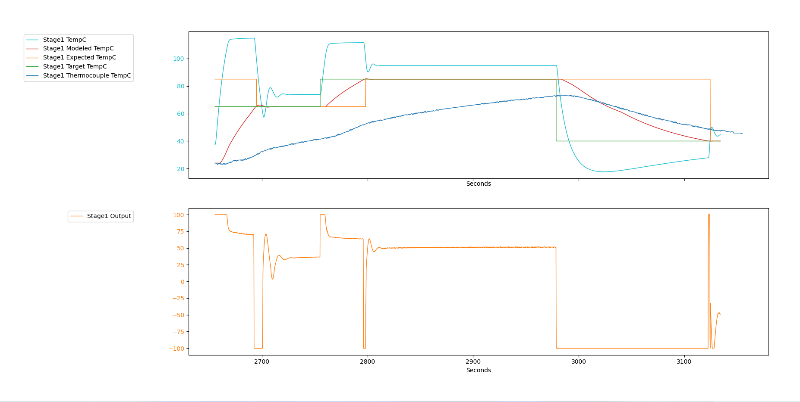
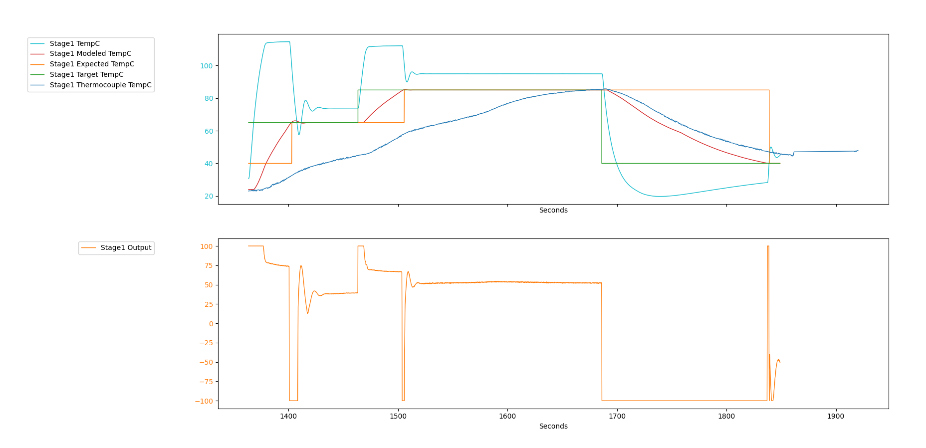
**Background**

The purpose of the treatment chamber in the At-Home PCR test is to treat a person’s saliva sample with Proteinase K (PK), an enzyme that cleaves proteins found in the saliva, like RNases, that may inhibit PCR. The PK is dried inside the treatment chamber and is hydrated by the user’s oral rinse. After the PK is hydrated, it needs to be activated and killed before the sample can be introduced to the PCR reagents. To activate the PK, the sample in the treatment chamber needs to be heated to about 65c for 60 seconds and to kill the PK it needs to reach at least 85c for 2 to 3 minutes.

The treatment chamber sits on top of an aluminum slug that is meant to transfer heat into the sample. The bottom of the chamber is a thin film that separates the slug from the sample and ideally the film will form around the slug creating uniform contact between the two surfaces. An example of the temperature data from an ideal scenario is shown on the right.

 Ideal contact is not always achieved for various reasons. Some potential causes are the vacuum in the chamber fails to equilibrate or the sleeve surrounding the cup absorbs the pressure induced by the cup hold down spring. Examples of temperature data from poor contact scenarios are shown below.



When the insert was introduced, it appeared to remedy the contact issue by manually pushing the film down against the slug and the thermal data was consistently within 5 degrees of the model (1). It also appeared that while the insert was improving thermal consistency, it was too tall for the PTC to seal consistently so the height was decreased to 4.6mm. Once the 4.6mm inserts were implemented there was an increase in thermal testing failures where the sample temperature was much lower than the model temperature and out of spec.

In an attempt to repeat the results from the failed tests, cups were filled while pushing against the bottom film up into the treatment chamber to simulate the scenario of poor contact. This was done for the taller and shorter inserts to compare and the data is shown below

<https://codx.sharepoint.com/:f:/s/ACIMaverick/EpzQt_1c5bhFrAGgkb5Xi6QBD4UgNQMuIK03s92VhpImNQ?e=YdbOKa> (original vbuild testing)

* Insert
* Different height insert/pedestal
* Sleeve/deck