

10 July 2019

Change Notification Memo: HEK 293 HCP ELISA Kit 3G, Cat # F650S Now Available
Importance: HIGH

Dear Customer,

This letter is to provide notification that we anticipate our current supply of capture and detection antibodies used in Catalog # F650R HEK 293 HCP ELISA kit will be depleted by the end of calendar year 2019. This is due to explosive growth in the number of cell and gene therapy development projects conducted by our customers. In response to this growth, Cygnus Technologies produced and characterized new antibodies for an ELISA format with enhancements to the current F650R kit performance. Kits containing the new antibodies and improved protocol are designated with a new kit catalog extension letter “S” as F650S. This notification is provided to your company in advance to allow time to plan and perform any bridging, re-qualification, or re-validation studies that you may deem necessary for transition to the new HEK 293 HCP antibody and corresponding F650S HEK 293 HCP ELISA.

The following table compares F650R and F650S assay design and specifications and highlights changes:

	F650R	F650S
Capture Antibody	Goat + Rabbit	Goat + Rabbit
Detection Antibody	Rabbit	Rabbit
Antigen	A mild lysate of HEK 293 cells extracted by a procedure similar to those used in propagating and harvesting cells producing viral vectors, followed by antigen processing using Cygnus proprietary method aimed to generate a broad immune response	Same extraction and processing method as for F650R antigen generation
Standards Diluent	I094	I700 *
Conjugate Diluent	I094	I085 *
Affinity Purified	Yes	Yes, identical procedure
Antibody coverage analysis as determined by AAE	68%	74%
LOD	~ 1 ng/mL	0.2 ng/mL
LOQ	~ 2 ng/mL	1 ng/mL
Precision	Intra-assay: 4.1 to 8.9 %CV Inter-assay: 6.1 to 10.8 %CV	Intra-assay: 4.2 – 7.1 %CV Inter-assay: 2.6 – 5.2 %CV
Accuracy	92.1 to 104.1%	90 – 99%
Simultaneous protocol	Yes	Yes
Detection Ab and Sample/ Standard/Control incubation time	2 h	1.5 h
Shelf Life	3 months	4 months

*New Diluents developed to enhance stability

Cygnus Technologies has evaluated these new antibodies in the ELISA using a panel of 25 process samples obtained from several customers. Most of the samples in our test panel gave less than a 2-fold difference between antibodies, some samples showed differences of up to 8-fold between the two assays. There was no trend for consistently higher or lower values in one assay or the other.

We suggest at least the following studies be performed to qualify the new F650S kit and corresponding capture antibody:

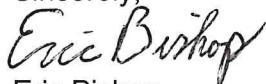
1. Establish the mean and acceptable range for your controls with the new F650S kit. These values may be different (higher or lower) relative to the current antibody. To avoid failing runs due to controls 'out of specification' it may be necessary to set a new range. If you use other curve parameters such as ODs as an indirect specification, these too may require a new range to be established.
2. Test previous in-process and drug substance samples using the new F650S kit to determine if there is a consistent and significant difference and bias (higher or lower values) from the new F650S kit.
3. Perform dilution linearity and spike recovery on your samples with the new antibodies to assure accuracy and specificity.
4. Orthogonal determination of coverage is best determined using our AAE method. We recommend performing AAE on at least two samples: 1) an upstream harvest sample to determine coverage to the majority of the proteome and 2) a down-stream sample to determine coverage those HCPs that persist through the purification process. Cygnus can perform the AAE analysis for you. Please note: Cygnus is offering a 20% discount on all AAE analysis requested in support of this change.
5. If you are using the F650R kit for lot release testing, determine what if any effect differences in control and sample values will have on your release criteria and document those changes.

Kits using the new antibody are now available, so that you can begin comparison studies. New kits are distinguished from old kits by the letter 'S' at the end of the catalog number. To order new kits, please specify catalog # F650S on the purchase order. The current F650R kits will be shipped until our supplies are exhausted.

Please forward a copy of this notification to those in your organization affected by this change.

Cygnus Technologies strives to provide you with the highest quality products and services, and we hope that this notification will result in as little disruption to your processes as possible. If you have any questions or concerns, please email technical services at techsupport@cygnustechnologies.com and we will be pleased to arrange teleconference.

Sincerely,



Eric Bishop
VP of R&D