

Attn.: Laboratory Manager**Reference number: PI000000273**

December 06, 2024

IMPORTANT FIELD ACTION NOTIFICATION**Subject: PD-L1 IHC 22C3 pharmDx, SK006 and PD-L1 22C3 pharmDx Kit (IUO), SK006**

Dear Valued Customer,

The purpose of this letter is to notify you that in certain lots of SK006, we have observed increased nonspecific background staining in the negative pellet of the control cell line slide and the tissue control slides. Failed controls may delay results if a retest is required; however, there is no observed impact in the accuracy of patient results.

Our records indicate that you may have received one or more affected SK006 kits. If you observe increased nonspecific background staining in the negative pellet of the control cell line slide or the tissue control slides, please contact Agilent, as indicated below, for troubleshooting assistance.

Description of the issue

Specific lots of SK006 have been reported to exhibit increased nonspecific background staining. Please see Table 1 on pages 3 and 4 for a list of affected lots. Agilent's Research & Development and Quality teams are actively investigating the issue and have identified a probable root cause. Further testing is being conducted, and we have taken actions to address the issue. You will be notified if any additional actions are required based on Agilent's investigation.

Evaluation of risk

The use of controls, as directed in the instructions for use (IFU), monitors assay performance to help confirm the assay is working as intended; the negative controls are used to identify nonspecific staining or background noise, such that only PD-L1 expression is detected. The risk of harm is deemed improbable, and there is no change to the validity of past test results.

Actions to be taken by the customer

1. If increased nonspecific background staining is observed, please contact Agilent technical support, your local sales representative, or Agilent Field Service Support.

2. Please confirm that you have received this information by signing and returning the enclosed Acknowledgement Form to fielddactions@agilent.com.

Transmission of this notice

We kindly ask you to inform those who need to be aware of this notification within your organization or any other organization to which the affected product(s) have been transferred. Please ensure that your organization maintains awareness of this notice.

Thank you for your attention to this matter. Please be assured that this issue has our full attention. We apologize for any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure customer satisfaction.

Sincerely,

**Brenda Tregellas**

VP, Global Quality & Regulatory Affairs, DGG
Agilent Technologies, Inc.
M. +1.408.386.7294
brenda.tregellas@agilent.com

**TABLE 1. Affected Products and Lot Numbers**

	Product Name	Part Number	Affected Lot Numbers
1	PD-L1 IHC 22C3 pharmDx	SK006	11548652, 11551363, 11551375, 11554787, 11560424, 11569784, 11573049, 11578788, 11579229, 11582506, 11583568, 11583578, 11585392, 11598089, 11600760, 11600773, 11602918, 11608824, 11608861, 11610808, 11617308, 11617331, 11621094, 11623133, 11623147, 11625040, 11628216, 11633269, 11633308, 11633320, 11636487, 11638255, 11646428, 11649200, 11650933, 11651456, 11654916, 11658160, 11658172, 11670029, 11670042, 11675213, 11677015, 11682471, 11682483, 11683536, 11683546, 11690259, 11693731, 11700906, 41569892, 41569920, 41575967, 41613697, 41613718, 41635778, 41635779, 41644182, 41644225, 41644277, 11551375A, 11551375B, 11551375C, 11551375D, 11551375E, 11554787A, 11554787B, 11554787C, 11554787D, 11554787E, 11554787F, 11554787G, 11554787H, 11554787I, 11554787J, 11554787K, 11560424A, 11560424B, 11560424C, 11569784A, 11569784B, 11569784C, 11569784D, 11569784E, 11569784F, 11569784G, 11578788A, 11578788B, 11578788C, 11578788D, 11578788E, 11579229A, 11579229B, 11579229C, 11583568A, 11583568B, 11583568C, 11583568D, 11583578A, 11585392A, 11585392B, 11585392C, 11585392D, 11585392E, 11585392F, 11585392G, 11585392H, 11585392I, 11598089A, 11598089B, 11598089C, 11598089D, 11598089E, 11598089F, 11600773A, 11600773B, 11600773C, 11600773D, 11600773E, 11600773F, 11602918A, 11602918B, 11602918C, 11602918D, 11608824A, 11608824B, 11608824C, 11608824D, 11608861A, 11608861B, 11608861C, 11608861D, 11608861E, 11608861F, 11608861G, 11617308A, 11617308B, 11617308C, 11617308D, 11617308E, 11617308F, 11617308G, 11617308H, 11617308I, 11617308J, 11617308K, 11617308L, 11617331A, 11617331B, 11617331C, 11617331D, 11617331E, 11617331F, 11617331G, 11617331H, 11617331I, 11621094A, 11621094B, 11621094C, 11621094D, 11623133A, 11623133B, 11623133C, 11623133D, 11623133E, 11623133F, 11623147A, 11623147B, 11623147C, 11623147D, 11623147E, 11623147F, 11625040A, 11625040B, 11625040C, 11625040D, 11625040E, 11625040F, 11625040G, 11625040H, 11625040I, 11625040J, 11625040K, 11625040L, 11633269A, 11633269B, 11633269C, 11633269D, 11633269E, 11633269F,



			11633269G, 11633308A, 11633320A, 11633320B, 11633320C, 11633320D, 11633320E, 11633320F, 11633320G, 11633320H, 11633320I, 11633320J, 11633320K, 11633320L, 11633320M, 11633320N, 11633320O, 11633320P, 11636487A, 11636487B, 11636487C, 11636487D, 11636487E, 11636487F, 11636487G, 11636487H, 11636487I, 11636487J, 11636487K, 11636487L, 11636487M, 11636487N, 11636487O, 11636487P, 11636487Q, 11646428A, 11646428B, 11646428C, 11646428D, 11646428E, 11646428F, 11649200A, 11649200B, 11649200C, 11649200D, 11649200E, 11649200F, 11649200G, 11649200H, 11654916A, 11654916B, 11654916C, 11658160A, 11658160B, 11658160C, 11658172A, 11658172B, 11658172C, 11658172D, 11658172E, 11658172F, 11670029A, 11670029B, 11670029C, 11675213A, 11682471A, 11682483A, 11682483B, 11682483C, 11682483D, 11682483E, 11682483F, 11682483G, 11690259A, 11693731A, 11693731B, 11693731C, 11693731D, 11693731E, 11700906A, 11700906B
2	PD-L1 22C3 pharmDx Kit (IUO)	SK006	11570065, 11608834, 11633292, 11667453, 11677344



Account name:
Account number:
Country:

Acknowledgment Form for Customers
Agilent Reference Number: PI000000273

Fill out this Acknowledgement Form to confirm receipt of the enclosed Field Action Notification regarding PD-L1 IHC 22C3 pharmDx, SK006, and PD-L1 22C3 pharmDx Kit (IUO), SK006.

Please complete the Acknowledgement Form within 7 days from receipt and email the form to fieldactions@agilent.com.

Acknowledgement:	
I have read and understood the Field Action Notification and the instructions stated in this letter:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Date	
Company/Laboratory name	
Name of person completing this form	
e-mail address	
Phone number	+
Signature	