

February 3, 2021

To health care providers,

ArcherDX, Inc. now Invitae*
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(Designated Marketing Approval Holder)
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Update on re-supply date for Archer[®]MET RNA (tissue) testing kits

This letter is to provide an update on the availability of Archer[®]MET RNA (tissue) testing, the companion diagnostic (CDx) system for Merck Biopharma's Tepmetko[®], a targeted therapy indicated for patients with METex14 skipping non-small cell lung cancer (NSCLC).

Archer[®]MET RNA (tissue) testing will be **unavailable** between February 3, 2021 and February 9, 2021. During this time, Archer[®]MET ctDNA kit is available as an alternative. We ask that medical institutions confirm ctDNA reimbursement during this period with the public welfare bureau in their respective regions.

Archer[®]MET RNA (tissue) testing kits are expected to be **available** for use beginning **February 10th, 2021**.

We also want to provide an update on the results of the root cause investigation for the lot that required further analysis. The evidence from our root cause investigation demonstrated a single component of the Archer[®]MET RNA (tissue) testing kit was operating at suboptimal performance.

This did not impact the final call for METex14 skipping; however, the overall performance agreement was below our designated threshold and out of an abundance of caution we didn't release the lot. We have replaced the component and completed our stringent quality control (QC) testing procedures. QC testing shows 100% overall percent agreement (OPA) with our reference material.

We deeply apologize for any inconvenience the delay in availability of Archer[®]MET RNA (tissue) testing may cause healthcare providers and patients. Thank you for your patience and understanding.

Contact regarding the content of this communication

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*ArcherDX Inc., the manufacturer of ArcherMET was acquired by Invitae in October 2020.