

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100		DATE(S) OF INSPECTION 2/2/2026-2/10/2026* FEI NUMBER 1000125183			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Susan D Hollandbeck, Quality Managment Representative					
FIRM NAME Ventana Medical Systems, Inc.		STREET ADDRESS 1910 E Innovation Park Dr			
CITY, STATE, ZIP CODE, COUNTRY Oro Valley, AZ 85755-1962		TYPE ESTABLISHMENT INSPECTED Manufacturer			
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.					
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Correction or corrective action resulting from the complaint handling process was not adequately documented. Specifically, both complaint handling procedures applicable to the complaints reviewed during this inspection, Customer Support Procedure MQMS-PM-GSP-03 (Ver 05, dated 30 July 2023) and Global Complaint Handling MQMS-PM-GSP-04 (Ver 06, dated 8 March 2024) require in the Case Closure section that <i>all relevant information</i>, including, but not limited to, the outcome and conclusion, are documented. In 2 of 5 complaint files reviewed (CAS-0020178849 and CAS-0022879637), however, the specific corrective actions implemented were not documented. Additionally, one complaint involving a protocol containing inaccurate information was incorrectly classified as an Inquiry (CAS-0019737772) instead of a Complaint, and neither the corrective action nor root cause was documented.					
OBSERVATION 2 Validation of processes for production and service provision did not adequately demonstrate the ability of the processes to achieve planned results consistently. Specifically, the process validation report for your firm's Ventana PTEN Assay, Report for PQ (pOQ & pPQ) Protocols for VENTANA PTEN (SP218) RxDx Assay, PN 740-7043 (completion date 12 Aug 2020), states in Section 1 that a small batch of product was required to be produced using the maximum mixing time (b)(4) min), however, the Batch Formulation Results table indicates that none of the (b)(4) batches were mixed for the maximum indicated time of (b)(4) minutes. Additionally, neither the report nor the associated protocols document a statistical rationale to support a sample size of (b)(4) (b)(4) pOQ and (b)(4) pPQ).					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Scott D Stevens, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> DATE ISSUED 2/10/2026 Scott D Stevens Investigator Signed By: 2004130571 Date Signed: 02-10-2026 16:57:01 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Scott D Stevens, Investigator	DATE ISSUED 2/10/2026 Scott D Stevens Investigator Signed By: 2004130571 Date Signed: 02-10-2026 16:57:01 X
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*DATES OF INSPECTION 2/02/2026(Mon), 2/03/2026(Tue), 2/04/2026(Wed), 2/05/2026(Thu), 2/06/2026(Fri), 2/10/2026(Tue)			
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Annotations to Observations Observation 1: Promised to correct Observation 2: Promised to correct			
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		DATE ISSUED 2/10/2026	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."