

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No...39..... dated 21/2/22 Regarding NCMDR FSN of Alinity s System from (mrf : Abbott).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 39 / 2022

20 -07-1443 H

21 -02-2022

ببمودة بثقة
Moving Forward
with Confidence

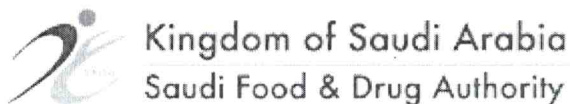


Field Safety Notice of Alinity s System from Abbott

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16020
Product	Alinity s System.
Description	Chemiluminescent immunoassay analyser IVD, automated.
Manufacturer	Abbott.
Affected	List Number (LN): 06P16-01 Serial Number: See Attachment A in the attached FSN.
Local Agent	Waleed Pharmacy & Stores LLC.
Reason	An error associated with the reagent probe (R1) wash cycle introduced in the Alinity s System software (SW) version 2.8.0. As a result of this error, while operating Alinity s System software version 2.8.0, LN 04U76-15, there is potential for false reactive Alinity s HIV Ag/Ab Combo test results when Alinity s HIV Ag/Ab Combo Reagent Kit, LN 06P0155, and the Alinity s Anti-HCV II Reagent Kit, LN 04W5655, are calibrated and run on the same processing lane.
Action	1. Please refer to "Necessary Actions to be Taken by Customer" in the attached FSN. 2. Abbott is developing a software update and will communicate when it is available. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL





Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Devices Sector

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NCMDR

National Center for Medical Devices Reporting


المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

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Reference Number: mdprc 009 02 22 000

Date submitted: 2/7/2022

Manufacturer:	Abbott
Device Type:	Alinity s System
Description:	Chemiluminescent immunoassay analyser IVD, automated
Medical Device Identifier:	List Number (LN): 06P16-01 Serial Number: See Attachment A in the attached FSN.
Reason of Field Safety Corrective Action:	An error associated with the reagent probe (R1) wash cycle introduced in the Alinity s System software (SW) version 2.8.0. As a result of this error, while operating Alinity s System software version 2.8.0, LN 04U76-15, there is potential for false reactive Alinity s HIV Ag/Ab Combo test results when Alinity s HIV Ag/Ab Combo Reagent Kit, LN 06P0155, and the Alinity s Anti-HCV II Reagent Kit, LN 04W5655, are calibrated and run on the same processing lane.
Remedy Action:	Please refer to "Necessary Actions to be Taken by Customer" in the attached FSN. Abbott is developing a software update and will communicate when it is available.
Athorized Representative/Importer/Distributor:	Medical supplies & Services Co.Ltd Mediserv
Report Source:	NCMDR
Source Ref. Number:	97B359A9D7323
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	 Abbott.pdf

[View History](#)

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Single Registration Number (SRN): N/A



Urgent Field Safety Notice
Urgent Product Correction
Immediate Action Required

Date Issued February 3, 2022

Product

Product Description	List Number (LN)	Serial Number	US/EU UDI
Alinity s System	06P16-01	See Attachment A	

Explanation

Abbott has identified an error associated with the reagent probe (R1) wash cycle introduced in the Alinity s System software (SW) version 2.8.0. The wash cycle removes fluid that remains on the interior and exterior surfaces of the probe at the wash station. The R1 probe wash is utilizing 1 mL versus the intended 3 mL of wash buffer to wash the exterior of the R1 probe.

As a result of this error, while operating Alinity s System software version 2.8.0, LN 04U76-15, there is potential for false reactive Alinity s HIV Ag/Ab Combo test results when Alinity s HIV Ag/Ab Combo Reagent Kit, LN 06P0155, and the Alinity s Anti-HCV II Reagent Kit, LN 04W5655, are calibrated and run on the same processing lane.

Impact on Donor/Patient Results

There is potential for incorrect Alinity s HIV Ag/Ab Combo test results should the initial and retest results be falsely reactive. For other assays, although there is potential for incorrect test results should the initial and retest results be falsely reactive, there have been no reports of falsely reactive results associated with this event. There is no potential for incorrect nonreactive results.

Necessary Actions to be Taken by Customer

Please perform the necessary immediate actions, if utilizing the Alinity s HIV Ag/Ab Combo and Alinity s Anti-HCV II assays while operating on Alinity s System SW version 2.8.0, to continue to use the Alinity s System. These actions mitigate potential impact for false reactive results when using the Alinity s HIV Ag/Ab Combo Reagent kit.

**Necessary
Actions to be
Taken by
Customer
continued**

If utilizing Alinity s System SW version 2.8.0	Then...
The Alinity s HIV Ag/Ab Combo and Alinity s Anti-HCV II assays are not installed or do not run on the same Alinity s System.	No action is required.
The Alinity s Anti-HCV II assay is not calibrated and run on the same processing lane as the Alinity s HIV Ag/Ab Combo assay.	Maintain the current assay configuration and ensure the Alinity s HIV Ag/Ab Combo assay is not run on the same processing lane as the Alinity s Anti-HCV II assay.
The Alinity s Anti-HCV II assay and the Alinity s HIV Ag/Ab Combo assay are calibrated and run on the same processing lane.	Contact your local area customer service representative to assess the configuration and uninstall/reinstall the assays to run on separate processing lanes or instruments.

If utilizing Alinity s System SW version 2.7.1 or prior, no further action is required.

Abbott is developing a software update and will communicate when it is available.

A complaint review and analysis of available data on the Alinity s System software version 2.8.0 was completed. There was no indication of incorrect test results attributable to the conversion from the Alinity s System software version 2.7.1 to version 2.8.0 for any assay other than Alinity s HIV Ag/Ab Combo.

Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported Alinity s HIV Ag/Ab Combo assay test results while operating on Alinity s System SW version 2.8.0.

If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.

Please complete and return the Customer Reply form and retain this letter for your laboratory records.

**Contact
Information**

If you or any of the health care providers you serve have questions regarding this information, please contact your local area Customer Service.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.

Attachment A SN UDI List – Product Correction Letter Version A

Part Description	List Number	Serial Number	UDI
Alinity s System	06P16	AS1001	(01)00380740138479(21)AS1001
Alinity s System	06P16	AS1004	(01)00380740138479(21)AS1004
Alinity s System	06P16	AS1006	(01)00380740138479(21)AS1006
Alinity s System	06P16	AS1007	(01)00380740138479(21)AS1007
Alinity s System	06P16	AS1008	(01)00380740138479(21)AS1008
Alinity s System	06P16	AS1015	(01)00380740138479(21)AS1015
Alinity s System	06P16	AS1017	(01)00380740138479(21)AS1017
Alinity s System	06P16	AS1022	(01)00380740138479(21)AS1022
Alinity s System	06P16	AS1026	(01)00380740138479(21)AS1026
Alinity s System	06P16	AS1027	(01)00380740138479(21)AS1027
Alinity s System	06P16	AS1029	(01)00380740138479(21)AS1029
Alinity s System	06P16	AS1030	(01)00380740138479(21)AS1030
Alinity s System	06P16	AS1033	(01)00380740138479(21)AS1033
Alinity s System	06P16	AS1034	(01)00380740138479(21)AS1034
Alinity s System	06P16	AS1035	(01)00380740138479(21)AS1035
Alinity s System	06P16	AS1036	(01)00380740138479(21)AS1036
Alinity s System	06P16	AS1037	(01)00380740138479(21)AS1037
Alinity s System	06P16	AS1038	(01)00380740138479(21)AS1038
Alinity s System	06P16	AS1039	(01)00380740138479(21)AS1039
Alinity s System	06P16	AS1040	(01)00380740138479(21)AS1040
Alinity s System	06P16	AS1041	(01)00380740138479(21)AS1041
Alinity s System	06P16	AS1042	(01)00380740138479(21)AS1042
Alinity s System	06P16	AS1043	(01)00380740138479(21)AS1043
Alinity s System	06P16	AS1045	(01)00380740138479(21)AS1045
Alinity s System	06P16	AS1046	(01)00380740138479(21)AS1046
Alinity s System	06P16	AS1047	(01)00380740138479(21)AS1047
Alinity s System	06P16	AS1048	(01)00380740138479(21)AS1048
Alinity s System	06P16	AS1049	(01)00380740138479(21)AS1049
Alinity s System	06P16	AS1050	(01)00380740138479(21)AS1050
Alinity s System	06P16	AS1051	(01)00380740138479(21)AS1051
Alinity s System	06P16	AS1052	(01)00380740138479(21)AS1052
Alinity s System	06P16	AS1053	(01)00380740138479(21)AS1053
Alinity s System	06P16	AS1054	(01)00380740138479(21)AS1054
Alinity s System	06P16	AS1056	(01)00380740138479(21)AS1056
Alinity s System	06P16	AS1057	(01)00380740138479(21)AS1057
Alinity s System	06P16	AS1063	(01)00380740138479(21)AS1063
Alinity s System	06P16	AS1065	(01)00380740138479(21)AS1065
Alinity s System	06P16	AS1066	(01)00380740138479(21)AS1066
Alinity s System	06P16	AS1067	(01)00380740138479(21)AS1067
Alinity s System	06P16	AS1068	(01)00380740138479(21)AS1068
Alinity s System	06P16	AS1070	(01)00380740138479(21)AS1070
Alinity s System	06P16	AS1071	(01)00380740138479(21)AS1071
Alinity s System	06P16	AS1072	(01)00380740138479(21)AS1072
Alinity s System	06P16	AS1073	(01)00380740138479(21)AS1073
Alinity s System	06P16	AS1074	(01)00380740138479(21)AS1074
Alinity s System	06P16	AS1075	(01)00380740138479(21)AS1075
Alinity s System	06P16	AS1076	(01)00380740138479(21)AS1076

Attachment A SN UDI List – Product Correction Letter Version A

Alinity s System	06P16	AS1078	(01)00380740138479(21)AS1078
Alinity s System	06P16	AS1079	(01)00380740138479(21)AS1079
Alinity s System	06P16	AS1080	(01)00380740138479(21)AS1080
Alinity s System	06P16	AS1081	(01)00380740138479(21)AS1081
Alinity s System	06P16	AS1083	(01)00380740138479(21)AS1083
Alinity s System	06P16	AS1084	(01)00380740138479(21)AS1084
Alinity s System	06P16	AS1085	(01)00380740138479(21)AS1085
Alinity s System	06P16	AS1086	(01)00380740138479(21)AS1086
Alinity s System	06P16	AS1087	(01)00380740138479(21)AS1087
Alinity s System	06P16	AS1088	(01)00380740138479(21)AS1088
Alinity s System	06P16	AS1089	(01)00380740138479(21)AS1089
Alinity s System	06P16	AS1090	(01)00380740138479(21)AS1090
Alinity s System	06P16	AS1091	(01)00380740138479(21)AS1091
Alinity s System	06P16	AS1092	(01)00380740138479(21)AS1092
Alinity s System	06P16	AS1093	(01)00380740138479(21)AS1093
Alinity s System	06P16	AS1094	(01)00380740138479(21)AS1094
Alinity s System	06P16	AS1095	(01)00380740138479(21)AS1095
Alinity s System	06P16	AS1096	(01)00380740138479(21)AS1096
Alinity s System	06P16	AS1098	(01)00380740138479(21)AS1098
Alinity s System	06P16	AS1099	(01)00380740138479(21)AS1099
Alinity s System	06P16	AS1100	(01)00380740138479(21)AS1100
Alinity s System	06P16	AS1101	(01)00380740138479(21)AS1101
Alinity s System	06P16	AS1103	(01)00380740138479(21)AS1103
Alinity s System	06P16	AS1104	(01)00380740138479(21)AS1104
Alinity s System	06P16	AS1107	(01)00380740138479(21)AS1107
Alinity s System	06P16	AS1108	(01)00380740138479(21)AS1108
Alinity s System	06P16	AS1109	(01)00380740138479(21)AS1109
Alinity s System	06P16	AS1110	(01)00380740138479(21)AS1110
Alinity s System	06P16	AS1111	(01)00380740138479(21)AS1111
Alinity s System	06P16	AS1113	(01)00380740138479(21)AS1113
Alinity s System	06P16	AS1114	(01)00380740138479(21)AS1114
Alinity s System	06P16	AS1115	(01)00380740138479(21)AS1115
Alinity s System	06P16	AS1116	(01)00380740138479(21)AS1116
Alinity s System	06P16	AS1117	(01)00380740138479(21)AS1117
Alinity s System	06P16	AS1118	(01)00380740138479(21)AS1118
Alinity s System	06P16	AS1119	(01)00380740138479(21)AS1119
Alinity s System	06P16	AS1120	(01)00380740138479(21)AS1120
Alinity s System	06P16	AS1121	(01)00380740138479(21)AS1121
Alinity s System	06P16	AS1122	(01)00380740138479(21)AS1122
Alinity s System	06P16	AS1123	(01)00380740138479(21)AS1123
Alinity s System	06P16	AS1124	(01)00380740138479(21)AS1124
Alinity s System	06P16	AS1127	(01)00380740138479(21)AS1127
Alinity s System	06P16	AS1128	(01)00380740138479(21)AS1128
Alinity s System	06P16	AS1129	(01)00380740138479(21)AS1129
Alinity s System	06P16	AS1130	(01)00380740138479(21)AS1130
Alinity s System	06P16	AS1131	(01)00380740138479(21)AS1131
Alinity s System	06P16	AS1132	(01)00380740138479(21)AS1132
Alinity s System	06P16	AS1133	(01)00380740138479(21)AS1133
Alinity s System	06P16	AS1134	(01)00380740138479(21)AS1134

Attachment A SN UDI List – Product Correction Letter Version A

Alinity s System	06P16	AS1135	(01)00380740138479(21)AS1135
Alinity s System	06P16	AS1138	(01)00380740138479(21)AS1138
Alinity s System	06P16	AS1139	(01)00380740138479(21)AS1139
Alinity s System	06P16	AS1146	(01)00380740138479(21)AS1146
Alinity s System	06P16	AS1147	(01)00380740138479(21)AS1147
Alinity s System	06P16	AS1149	(01)00380740138479(21)AS1149
Alinity s System	06P16	AS1150	(01)00380740138479(21)AS1150
Alinity s System	06P16	AS1151	(01)00380740138479(21)AS1151
Alinity s System	06P16	AS1152	(01)00380740138479(21)AS1152
Alinity s System	06P16	AS1154	(01)00380740138479(21)AS1154
Alinity s System	06P16	AS1156	(01)00380740138479(21)AS1156
Alinity s System	06P16	AS1157	(01)00380740138479(21)AS1157
Alinity s System	06P16	AS1158	(01)00380740138479(21)AS1158
Alinity s System	06P16	AS1159	(01)00380740138479(21)AS1159
Alinity s System	06P16	AS1162	(01)00380740138479(21)AS1162
Alinity s System	06P16	AS1163	(01)00380740138479(21)AS1163
Alinity s System	06P16	AS1164	(01)00380740138479(21)AS1164
Alinity s System	06P16	AS1165	(01)00380740138479(21)AS1165
Alinity s System	06P16	AS1166	(01)00380740138479(21)AS1166
Alinity s System	06P16	AS1167	(01)00380740138479(21)AS1167
Alinity s System	06P16	AS1168	(01)00380740138479(21)AS1168
Alinity s System	06P16	AS1169	(01)00380740138479(21)AS1169
Alinity s System	06P16	AS1170	(01)00380740138479(21)AS1170
Alinity s System	06P16	AS1171	(01)00380740138479(21)AS1171
Alinity s System	06P16	AS1172	(01)00380740138479(21)AS1172
Alinity s System	06P16	AS1173	(01)00380740138479(21)AS1173
Alinity s System	06P16	AS1174	(01)00380740138479(21)AS1174
Alinity s System	06P16	AS1175	(01)00380740138479(21)AS1175
Alinity s System	06P16	AS1176	(01)00380740138479(21)AS1176
Alinity s System	06P16	AS1177	(01)00380740138479(21)AS1177
Alinity s System	06P16	AS1178	(01)00380740138479(21)AS1178
Alinity s System	06P16	AS1179	(01)00380740138479(21)AS1179
Alinity s System	06P16	AS1180	(01)00380740138479(21)AS1180
Alinity s System	06P16	AS1181	(01)00380740138479(21)AS1181
Alinity s System	06P16	AS1182	(01)00380740138479(21)AS1182
Alinity s System	06P16	AS1183	(01)00380740138479(21)AS1183
Alinity s System	06P16	AS1184	(01)00380740138479(21)AS1184
Alinity s System	06P16	AS1185	(01)00380740138479(21)AS1185
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Alinity s System	06P16	AS1187	(01)00380740138479(21)AS1187
Alinity s System	06P16	AS1197	(01)00380740138479(21)AS1197
Alinity s System	06P16	AS1203	(01)00380740138479(21)AS1203
Alinity s System	06P16	AS1204	(01)00380740138479(21)AS1204
Alinity s System	06P16	AS1205	(01)00380740138479(21)AS1205
Alinity s System	06P16	AS1206	(01)00380740138479(21)AS1206
Alinity s System	06P16	AS1207	(01)00380740138479(21)AS1207
Alinity s System	06P16	AS1208	(01)00380740138479(21)AS1208
Alinity s System	06P16	AS1209	(01)00380740138479(21)AS1209
Alinity s System	06P16	AS1210	(01)00380740138479(21)AS1210

Attachment A SN UDI List – Product Correction Letter Version A

Alinity s System	06P16	AS1211	(01)00380740138479(21)AS1211
Alinity s System	06P16	AS1214	(01)00380740138479(21)AS1214
Alinity s System	06P16	AS1216	(01)00380740138479(21)AS1216
Alinity s System	06P16	AS1223	(01)00380740138479(21)AS1223
Alinity s System	06P16	AS1228	(01)00380740138479(21)AS1228
Alinity s System	06P16	AS1229	(01)00380740138479(21)AS1229
Alinity s System	06P16	AS1232	(01)00380740138479(21)AS1232
Alinity s System	06P16	AS1308	(01)00380740138479(21)AS1308
Alinity s System	06P16	AS1328	(01)00380740138479(21)AS1328
Alinity s System	06P16	AS1329	(01)00380740138479(21)AS1329
Alinity s System	06P16	AS1331	(01)00380740138479(21)AS1331
Alinity s System	06P16	AS1337	(01)00380740138479(21)AS1337
Alinity s System	06P16	AS1338	(01)00380740138479(21)AS1338
Alinity s System	06P16	AS1339	(01)00380740138479(21)AS1339
Alinity s System	06P16	AS1340	(01)00380740138479(21)AS1340
Alinity s System	06P16	AS1342	(01)00380740138479(21)AS1342
Alinity s System	06P16	AS1343	(01)00380740138479(21)AS1343