



Product Recall

Urgent - Immediate Action Required

Date Issued November 26, 2019

Product

Product Name	List Number	Lot Number	Expiration Date	UDI Number
ARCHITECT Reaction Vessels	7C15-03	See Table 1	N/A	N/A

Explanation

We have observed an increase in complaints due to static discharge in the ARCHITECT Reaction Vessel (RV) on the ARCHITECT i2000, i2000SR, and i1000SR at the optics reader. The static discharge can result in Error Code 1007 (Unable to process test, activated read failure) or potentially falsely elevated or false positive patient results when using the ARCHITECT RV lots listed in Table 1.

Static discharge impacts direct assays as the lower relative light unit (RLU) counts for direct assays could be impacted by the additional RLUs introduced by these static discharge spikes. A list of ARCHITECT Immunoassays that are considered direct assays can be found in Table 2.

Patient Impact

There is potential impact to patient results (falsely elevated or false positive results) if the static discharge occurs without generating an error code.

Necessary Actions

Determine if you have any of the lots listed in your inventory or in use on your analyzer. Refer to Table 1.

- If you **DO NOT** have any of these lots in your inventory or in use on your analyzer, no action is required.
- If you **DO** have any remaining inventory of these lots or are unable to determine the lot number in use, immediately discontinue use and discard according to your laboratory procedures. Contact Customer Support to order replacement RVs.
- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
- If you have forwarded any of the products listed within this letter to other laboratories, please inform them of this Product Recall and provide them a copy of this letter.
- Complete and return the Customer Reply Form.
- Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have any 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.

Table 1
Impacted ARCHITECT RV Lot numbers

Distribution of these lots started in September 2018. This product was only shipped to the following countries: Japan, Philippines, Singapore, Hong Kong, Taiwan, Malaysia, China, South Korea, Australia, New Zealand, Thailand

000128930	000159040	000168134	000183583	000190801	000198142	000213273
000129137	000158817	000168135	000182420	000189686	000198979	000212327
000146408	000160074	000170243	000181523	000189682	000200183	000211079
000146787	000156697	000170235	000180946	000191602	000199628	000211874
000148299	000157916	000170118	000172952	000190802	000201033	000212900
000149564	000156214	000170789	000177120	000191603	000202929	000213274
000147027	000160593	000170234	000177121	000189344	000202096	000213759
000148301	000160592	000171785	000172459	000194877	000202931	000214881
000148914	000161603	000173596	000175783	000195140	000204777	000213760
000148912	000157629	000172458	000180945	000195107	000205072	000215401
000151451	000161931	000174183	000179280	000192553	000205754	000216109
000150649	000161604	000170788	000179796	000193160	000206784	000216671
000151450	000162145	000171767	000182421	000192552	000207369	000217400
000149652	000162908	000170242	000183058	000193161	000207900	000215711
000152068	000165220	000172968	000180441	000193795	000208900	000216414
000152328	000165229	000173603	000181522	000187552	000204198	000219624
000153326	000163423	000170117	000183582	000196528	000206983	000218661
000153985	000163862	000174129	000185122	000195911	000207041	000217788
000153325	000164737	000174182	000184515	000197420	000207899	000220585
000155352	000163861	000175053	000184555	000198141	000208468	000218354
000155049	000162907	000177123	000183095	000193794	000203708	000219545
000156213	000163397	000175785	000186959	000197419	000204197	000217437
000147606	000165598	000177124	000185476	000195141	000205071	000220582
000155050	000166191	000178723	000186087	000196199	000205753	000221880
000153987	000166189	000175443	000187839	000196529	000209113	000223337
000155353	000167367	000175054	000181983	000198980	000209841	000226081
000158149	000166701	000175441	000186937	000201126	000210146	000224765
000159039	000167342	000175784	000188075	000199627	000209399	000225646
000160073	000168136	000179279	000186935	000200184	000210447	000226437
000158816	000169478	000179797	000185477	000202097	000211413	
000156866	000167913	000174130	000186557	000201260	000210103	
000157630	000169477	000175782	000189342	000201259	000214877	

Table 2
Direct assays for ARCHITECT IA systems

List Number	Product Name	List Number	Product Name	List Number	Product Name
01P37	ARCHITECT Urine NGAL	03P65	ARCHITECT EBV VCA IgG	06P22	ARCHITECT BRAHMS PCT
01P45	ARCHITECT ProGRP	03P66	ARCHITECT EBV VCA IgM	06P32	NSE
01P65	ARCHITECT Anti-CCP	03P67	ARCHITECT EBV EBNA-1 IgG	07C18	ARCHITECT Anti-HBs
02G22	ARCHITECT HBsAg Qualitative II	04J27	ARCHITECT HIV Ag/Ab Combo	07K59	ARCHITECT Ferritin
02G23	ARCHITECT HBsAg Qualitative II Confirmatory	04P72	ARCHITECT HbA1C	07K62	ARCHITECT TSH
02K41	ARCHITECT STAT Troponin-I	04P76	ARCHITECT HBsAg Next Qualitative	07K67	ARCHITECT AFP
02K42	ARCHITECT STAT CK-MB	04P77	ARCHITECT HBsAg Next Confirmatory	07K68	ARCHITECT CEA
02K43	ARCHITECT STAT MYOGLOBIN	05P03	ARCHITECT Galectin-3	07K70	ARCHITECT Total PSA
02K44	ARCHITECT CA 15-3	05P20	ARCHITECT Thyroglobulin	07K71	ARCHITECT Free PSA
02K45	ARCHITECT CA 125 II	06C15	ARCHITECT CMV IgG	07K75	ARCHITECT FSH
02K46	ARCHITECT Anti-Tg	06C16	ARCHITECT CMV IgM	07K76	ARCHITECT Prolactin
02K47	ARCHITECT Anti-TPO	06C17	ARCHITECT Rubella G	07K78	ARCHITECT Total B-hCG
02K48	ARCHITECT T-Uptake	06C18	ARCHITECT Rubella IgM	07P24	ARCHITECT HBeAg Quantitative
02K91	ARCH CA19-9 XR	06C19	ARCHITECT Toxo IgG	08D06	ARCHITECT Syphilis TP
02P25	ARCHITECT Chagas	06C20	ARCHITECT Toxo IgM	08D07	ARCHITECT Pepsinogen I
02P40	ARCHITECT LH	06C25	ARCHITECT LH	08D18	ARCHITECT SCC
02P48	ARCHITECT PIVKA-II	06C29	ARCHITECT HAVAb-IgG	08K25	ARCHITECT Intact PTH
02P54	ARCHITECT HE4	06C30	ARCHITECT HAVAb-IgM	08K26	ARCHITECT SHBG
02P55	ARCHITECT CYFRA 21-1	06C32	ARCHITECT HBeAg	08K28	ARCHITECT BNP
02R10	Alere NT-proBNP for ARCHITECT	06C33	ARCHITECT Anti-HBc IgM	08K41	ARCHITECT Insulin
03L46	ARCHITECT CMV IgG Avidity	06C36	ARCHITECT HBsAg	08L11	ARCHITECT MPO
03L53	ARCHITECT C-Peptide	06C37	ARCHITECT Anti-HCV	08L44	ARCHITECT Anti-HBc II
03P24	ARCHITECT Active-B12 (Holotranscobolamin)	06L37	ARCHITECT Toxo IgG Avidity	09C94	ARCHITECT HBsAg Confirmatory V.1
03P25	ARCHITECT STAT High Sensitive Troponin-I	06L47	ARCHITECT HCV Ag	09D65	ARCHITECT Pepsinogen II
03P36	ARCHITECT AFP	06L61	ARCHITECT rHTLV-I/II		

Note: Not all products are available in all countries.