Preliminary Report: Discordant Results between COVID-19 Point of Care Antigen and PCR Tests in Nursing Homes

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Executive Summary

The American Health Care Association (AHCA) and LeadingAge conducted a joint survey of their skilled nursing facility (SNF) members to explore reports of discordant results between COVID-19 point of care (POC) antigen tests and PCR tests. A discordant results refer to a differing test result between a POC antigen test and PCR test using samples taken the same or next day from the same individual. The focus of this report are positive POC antigen results with a negative PCR confirmation test (referred to as discordant results throughout).

The majority (N= 939) SNF's reporting using either one of the two POC test devices (BD Veritor - 87% & Quidel Sofia-2 - 13%) distributed by the U.S. Department of Health and Human Services (HHS). The others either had not received the POC test devices yet or were not using them. Among the 817 SNFs that reporting using the BD Veritor, 293 conducted confirmation tests with PCR. Approximately 20% (N = 56) of these SNFs reported not seeing any discordant results. Approximately 80% reported that at least one or more of their positive antigen tests come back as a negative when a PCR confirmation test was conducted. About 25 facilities had over 6 discordant results.

Among the 119 SNFs that used the Quidel Sofia-2, 38 conducted confirmation tests. Eleven SNFs reported no discordant test results (29%). Approximately 71% of SNFs had at least one or more discordant results. Only one facility had over six discordant results.

We calculated the number of discordant results and compared that number to the predicted number of false positives assuming a 98% specificity with 1% disease prevalence. The numbers of discordant results was essentially the same as the predicted number of false positives (i.e., BD staff tests 650 vs 503 discordant vs predicted respectively; residents 310 vs 210; and Quidel staff 69 vs 63; residents 63 vs 210) among the facilities performing confirmation testing.

Conclusion

The majority of SNFs reporting discordant results had less than five, which would be expected with the widespread use of a test with 98% specify in a population with low disease prevalence. A small proportion reported a larger number of discordant test results (>6 per SNF), which warrants an investigation to determine if there was a problem. Reasons for discordant tests results could range from compliance with following the manufacturers protocols (common reason seen in the past), false negatives with the confirmation PCR tests (common reason seen in the past) or some issue with the tests kits or analyzers themselves (not seen in prior investigations) or yet some other factor.

Recommendation

We recommend continuing to use these POC devices for widespread testing in SNFS. However, these results underscore the importance of following manufactures protocols and CDC recommendations to conduct confirmation testing when antigen tests are positive among asymptomatic individuals. CMS and CDC also need to develop clearer guidance on what providers should do when the antigen test and confirmation tests are discordant with respect to patient care decisions, cohorting decisions, family notifications, NHSN reporting, and triggering an outbreak investigation.

Detailed Findings

LeadingAge and AHCA conducted a survey of members about their results from using POC antigen tests to explore reports of discordant test results. The survey was distributed widely to the membership of both organizations through emails, blog posts and by state affiliates. The survey was sent out on the morning of September 14, 2020 with a deadline for completion the next day, September 15 at midnight. Overall 1,281 facilities respond, of which 939 had received and used a POC antigen test.

The majority of respondents were using the BD Veritor consistent with reports that HHS mailed more BD devices to SNFs than the Quidel Sofia-2 device.

Device	%	N
BD	87%	820
Quidel	13%	119
	Total	939

We asked each SNF how many had a positive antigen test for staff and for residents. About 60% of SNFs using either device had no positive tests among staff and 80% of SNFs had no positive test among residents (see tables below). The distribution of positive tests for each device are shown below with about 5-8% of SNFs reporting more than 6 positive tests among staff or residents.

# of SNFs reporting Staff positive tests

# Positive Tests	0		1-5		6-15		over 15			Total*
	%	#	%	#	%	#	%	#		#
BD	59%	482	36%	296	4%	30	1%	9		817
Quidel	58%	69	34%	40	5%	6	3%	4		119

# of SNFs reporting Resident positive tests

# Positive Tests	0		1-5		6-15		over 15			Total*
	%	#	%	#	%	#	%	#		#
BD	82%	672	14%	115	2%	20	1%	8		815
Quidel	75%	88	17%	20	5%	6	3%	4		118

*excludes 1 to 5 SNFs who skipped the questions

We asked how many tests kits they had on hand. Almost 20% had run out and half had 1-2 week supply available. This is consistent with reports about shortages and difficulty in ordering replacement kits as manufacturing or replacement test kits catches up with demand.

Availability of tests kits

	Run out		1-2 week supply		>2 week supply		
	N	%	N	%	N	%	
BD	151	19%	431	54%	215	27%	
Quidel	16	14%	53	45%	48	41%	

N = 914 with 25 missing who did not respond to the question

We asked their current turnaround time for PCR tests. Only about half of SNFs could get results within 48 hours (recommended turn-around time from CMS and CDC). Among all respondents, 12% reported PCR test results were taking 5 or more days to arrive.

Turn around time for PCR tests					
	1-2 days	3 days	4 days	5 days	>5 days
# SNFs	472	236	92	45	66
% of SNFs	52%	26%	10%	5%	7%
	N = 911 with 28 missing who did not respond to the survey				

Exploring "Discordant Test Results"

We asked SNFs if they performed confirmation testing with PCR and, if so, to indicate the % of positive antigen tests that were discordant with PCR test (e.g. the confirmation PCR test was negative). The confirmation PCR tests were conducted either the same day or the next day following the antigen test. SNFs reported conducting confirmation tests for various reasons, including:

- Experiencing a larger number of positive tests than experienced prior to using the POC antigen test devices,
- Concern that the antigen tests might not be as accurate;
- Confirming a new test or piece of equipment; or
- Following CDC guidance to conduct a confirmatory PCR test when the antigen test is performed on an asymptomatic individual, particularly in low prevalence communities.

Among the 817 SNFs that used the BD Veritor, 293 conducted confirmation tests. Approximately 75% of SNFs had at least one or more of their positive antigen tests return as negative upon a confirmatory PCR test. About 25 facilities had over 6 positive tests return as negative upon confirmatory PCR. Fifty-six had no false positive tests (19%). This pattern was the same among tests performed for residents. (see tables below)

Among the 119 SNFs that used the Quidel Sofia-2, 38 conducted confirmation tests. Approximately 71% of SNFs had at least one or more of their antigen tests return as negative upon a confirmatory PCR test . Only one facility had over 6 positive tests return as negative upon a confirmatory PCR test . 11 SNFs had no false positive tests (29%). This pattern was the same among tests performed for residents. See tables below.

BD (SNFs who performed confirmation tests with PCR)

		# of SNFs with # of Positive tests among **Staff**									
		0		1-5		6-15		over 15		Total	
% of False Positives	None	3%	9	16%	46	0.3%	1	0.0%	0	19%	56
	1-5%	3%	9	18%	52	0.7%	2	0.3%	1	22%	64
	6%-10%	0%	0	1%	2	0.3%	1	0.3%	1	1%	4
	>10%	7%	21	42%	123	6.8%	20	1.7%	5	58%	169
	Total	13%	39	76%	223	8.2%	24	2.4%	7	100%	293

		# of SNFS with # of postive tests among **Residents**									
		0		1-5		6-15		over 15		Total	
% of False Positives	None	14%	40	5%	14	1%	3	0%	1	20%	58
	1-5%	13%	38	7%	20	1%	4	1%	2	22%	64
	6%-10%	0%	1	1%	2	0%	0	0%	1	1%	4
	>10%	37%	109	17%	49	2%	7	1%	3	57%	168
	Total	64%	188	29%	85	5%	14	2%	7	100%	294

Quidel (SNFs who performed confirmation tests with PCR)

		# of Positive tests among **Staff**									
		0		1-5		6-15		over 15		Total	
% of False Positives	None	2.6%	1	21.1%	8	5.3%	2	0.0%	0	29%	11
	1-5%	5.3%	2	21.1%	8	2.6%	1	2.6%	1	32%	12
	6%-10%	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0%	0
	>10%	7.9%	3	28.9%	11	2.6%	1	0.0%	0	39%	15
	Total	15.8%	6	71.1%	27	10.5%	4	2.6%	1	100%	38

		# of postive tests among Residents									
		0		1-5		6-15		over 15		Total	
% of False Positives	None	16%	6	11%	4	3%	1	0%	0	29%	11
	1-5%	18%	7	3%	1	5%	2	5%	2	32%	12
	6%-10%	0%	0	0%	0	0%	0	0%	0	0%	0
	>10%	18%	7	18%	7	3%	1	0%	0	39%	15
	Total	53%	20	32%	12	11%	4	5%	2	100%	38

Comparing Discordant Results with Predicted False Positives

We calculated the number of discordant test results among SNFs that reported conducting confirmation testing. We used the midpoint for the reported range of positive tests multiplied by the number of SNFs (e.g. used 3 for range of FP 1-5; 10 for range 6-15 and used 15 for >15). We calculated the number of discordant tests under two different assumptions: first that 100% of all tests were discordant regardless of the SNFs reported % of test at false positives (a worst case scenario) and second that 75% of positive tests were discordant. The second assumption is consistent with communications the two organizations were receiving from members who had conducted confirmation tests that at least three quarters or more of all of their POC positives tests were discordant. This was likely skewed by reporting bias since those without discordant tests were not contacting use. This is confirmed by the survey results. At least 20-30% of SNFs who conducted confirmation testing reported zero discordant results and many more reported that not all positive tests were discordant but given the nature of the question we could not

exactly calculate that number. In either case, our assumptions of 75% or 100% of all positive antigen tests is at the very high end or worst case scenario.

We calculated the predicted number of false positives among all the SNFs reporting that they performed confirmation testing. We assumed a specificity of 98% and disease prevalence of 1%. We assumed a 100 people were tested in each facility. The results of our comparison between the calculated number of false positives and predicted number are shown below.

Assuming 100% of tests were discordant, the number of discordant antigen tests was about 1.8 times higher than predicted for BD and 1.5 for Quidel for staff but was less than predicted for residents. If we change that assumption to 75% of positive tests were discordant, then the numbers of discordant tests was essentially the same as the predicted number of false positives (i.e., BD staff 650 vs 503 calculated vs predicted respectively; residents 310 vs 210 and Quidel staff 69 vs 63; residents 63 vs 210) among the facilities performing confirmation testing with PCR.

# of Discordant Results (**100%** assumption)		
	BD	Quidel
Staff	866	92
Residents	413	84
Total	1279	176

Assuming 100% of all positive tests were discordant and calculated # of discordant tests using the midpoint for reported ranges of discordant tests reported by each SNF

# of Discordant Results (**75%** assumption)		
	BD	Quidel
Staff	650	69
Residents	310	63
Total	960	132

Assuming 75% of all positive tests were discordant and calculated # of discordant tests using the midpoint for reported ranges of discordant tests reported by each SNF

Predicted # of False Positive Tests		
	BD	Quidel
Staff	503	63
Residents	210	210
Total	713	273

Assuming test specificity of 98% with disease prevalence of 1% and 100 antigen tests performed per SNF who conducted confirmation testing

Conclusion

The majority of SNFs reporting discordant results had less than five per SNF, which would be expected with the widespread use of a test with 98% specify in a population with low disease prevalence. A small proportion reported a larger number of discordant test results (>6 per SNF), which warrant an investigation to determine if there was a problem. Reasons for discordant tests results could range from compliance with following the manufacturers protocols (common reason seen in the past), false negatives with the confirmation PCR tests (common reason seen in the past) or some issue with the tests kits or analyzers themselves (not seen in prior investigations) or yet some other factor.

The issue of discordant test results is to be expected when either antigen or PCR tests are used properly and functioning properly, which will continue as new manufacture's products become available since in practice, all of these tests will not have 100% specificity. Currently, clear guidance from CMS or CDC or FDA on how providers should respond and treat patients with discordant results is lacking.

Recommendation

We recommend continuing to use antigen POC devices for widespread testing in skilled nursing facilities. However, we strongly recommend that providers take the following steps:

1. **Complete manufactures training**
    a. Quidel Sofia 2: https://togetheragain.quidel.com/
    b. BD Veritor TM System: https://www.bdveritor.com/
2. **Confirm they are following the manufactures protocols**
3. **Follow CDC recommendation on confirming antigen test results**
    a. This includes conducting confirmation testing when antigen tests are positive among asymptomatic individuals
4. **Report discordant results to the manufacturers**

    For BD Veritor potential false positives providers should:
    - Call 1-800-638-8663 for providers who experience potential false positives (note: press 2 for technical support and then 1 for Veritor support); or
    - Email BD at Technical_Services@bd.com

    For Quidel potential false positives, providers should:
    - Call 1-800-874-1517, option 2, then option 1 for providers who experience potential false positives
    - Email Quidel at Technical Support (Quidel San Diego) technicalsupport@quidel.com

CMS and CDC also need to develop clearer guidance on what providers should do when the antigen test and confirmation tests are discordant with respect to patient care decisions, cohorting decisions, family notifications, NHSN reporting, and triggering an outbreak investigation.