

Lab Risk Assessment for Philippine Genome Center - Clinical Genomics Laboratory										Ver.1.1 as of 30 Mar 202	
SR#	Area	Activity/Process	Quality Concerns / Risks	Initial Risk Assessment			Existing Controls	Residual Risk Assessment			Further Controls Needed
				Severity Rating	Likelihood	Risk Rating		Severity Rating	Likelihood	Risk Rating	
1	Field Activities	Sample Collection	Inactivation of nasopharyngeal/oropharyngeal swab specimen - risk of infection	5	4	20	On-site heat inactivation (water bath or dry heat) 60 degrees C for at least 30 minutes after sealing with parafilm; procedure done prior to transport	2	2	4	
2	Lab Activities	Sample collection	Mislabeling of specimen	4	3	12	Patient identifiers with printed labels including the following details: Name, Patient ID, specimen type, date collected Sample collection sheet forwarded to receiving section, who performs a readback to confirm the contents of each labeled specimen to their respective patient identifiers.	5	1	5	Reject samples with incomplete/unverifiable patient identifiers.
3	Lab Activities	Sample collection	Samples proceed outside of quarantined sections of the facility	3	3	9	Samples are inactivated prior to arrival at the facility; dedicated receiving bay separate to main entrance with direct access to the testing lab via the service elevator, bypassing sections of the facility outside of the quarantined area.	2	1	2	
4	Lab Activities	RNA Extraction	Overflowing of tips in amber biohazard bags resulting in puncture and spillage	2	4	8	Placement of "do not overfill" sign and indicator line on bag to encourage early replacement of amber biohazard bags	1	2	2	
5	Lab Activities	RNA Extraction	Spillage of used tips in amber biohazard bags upon sealing	2	4	8	Use of a handheld sealer to close the bag in an upright fashion	1	1	1	
6	Lab Activities	Test Performance	Inundation of staff due to number of tests performed resulting in errors	4	3	12	Limit number of tests performed to 20 per shift per staff member; keep staff at specific test stage stations to minimize errors	2	2	4	
7	Lab Activities	Test Performance	Inexperience of volunteers working in COVID-19 screening lab	3	4	12	Buddy system with experienced staff member for every shift to facilitate checking and learning of protocols; evaluation and screening of volunteers prior to inclusion in workforce	2	3	6	Hire additional staff to reduce reliance on volunteers
8	Lab Equipment	Autoclave	Improper disinfection of used equipment	2	2	4	Monthly calibration to assure appropriate function	1	1	1	
9	Lab Equipment	N95 masks (PPE)	Poor fit of masks on laboratory staff (failed "fit-ness test")	4	4	16	Assign staff that fail "fit-ness test" to areas not requiring N95 mask PPE	1	1	4	
10	Lab Equipment	Biosafety cabinet	Failure due to power outage	4	2	8	BSC certified and hooked to UPS with AVR; backup generators with 16 hours operational capacity (<8 second delay)	1	1	1	
11	Lab Layout	Access	Shared entrance with neighboring laboratory	1	4	4	Deny access to other facilities on the third floor (location of COVID-19 screening lab) until interim segregation panel is placed to limit access to authorized personnel only	1	1	2	

Risk Matrix

Risk Assessment Matrix					
Level of Risk					
Probability	Impact				
	Very Low (1)	Low (2)	Medium (3)	High (4)	Very High (5)
Very High (5)	5	10	15	20	25
High (4)	4	8	12	16	20
Medium (3)	3	6	9	12	15
Low (2)	2	4	6	8	10
Very Low (1)	1	2	3	4	5

Value	Probability	Definition
5	Very High	At least once a day
4	High	At least once a week
3	Medium	At least once a month
2	Low	At least once every 6 months
1	Very Low	At least once a year or rarely

Value	Impact	Definition
1	Very Low	Little to no impact on testing activities or to the personnel performing the activity
2	Low	Minimal changes to work environment resulting in delays in testing activity
3	Medium	Medium impact due to changes in work environment and/or equipment resulting in ambiguous/inaccurate test results
4	High	Marked impact due to high personal risk on personnel performing activities resulting in threat to health and safety or great compromise to the operations of the facility
5	Very High	Very high impact that directly results in injury to personnel involved and can potentially disrupt all operations