

From: Shakespeare, Penny
To: s22, Lucrese, Renave
Subject: FW: Promedical POCT [SEC=OFFICIAL]
Date: Friday, 20 March 2020 8:33:36 PM

Penny Shakespeare | Deputy Secretary, Health Financing Group | Department of Health ☎ 02 6289 3348 | s22 | ✉ penny.shakespeare@health.gov.au

From: Shakespeare, Penny
Sent: Friday, 20 March 2020 8:31 PM
To: 'Neran De Silva' <neran@promedical.com.au>
Cc: s22 @health.gov.au
Subject: FW: Promedical POCT [SEC=OFFICIAL]

Hello again Neran.

On behalf of the Australian Government I would like to procure the following, with payment on delivery:

To be delivered by	1 April 2020
Promedical COVID-19 Rapid Test kit @\$13.90 per test kit	500,000 – to be delivered by 1 April 2020

If you agree please let me know and I will have the contract for formal execution of the agreement tomorrow.

Regards
Penny

Penny Shakespeare | Deputy Secretary, Health Financing Group | Department of Health ☎ 02 6289 3348 | s22 | ✉ penny.shakespeare@health.gov.au

From: Neran De Silva <neran@promedical.com.au>
Sent: Friday, 20 March 2020 11:54 AM
To: Shakespeare, Penny <Penny.Shakespeare@health.gov.au>
Cc: Cassandra Auty <cassandra@promedical.com.au>
Subject: Re: Promedical POCT [SEC=OFFICIAL]

Hi Penny,

Yes we would like to proceed.
 Pease send the PO so we will issue the sales contract and the invoice .

Yes we can continue discussions for long term agreement.

Kind Regards
Neran

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Thanks Neran

As discussed, we would like to place an order for 500,000 units at the quoted price, and continue discussing ongoing, longer-term order volumes. If this is acceptable, we will issue an initial purchase order to you today.

Penny Shakespeare | Deputy Secretary, Health Financing Group | Department of Health ☎ 02 6289 3348 | s22 [REDACTED] ✉ penny.shakespeare@health.gov.au

From: Neran De Silva <neran@promedical.com.au>
Sent: Friday, 20 March 2020 11:04 AM
To: Cassandra Auty <cassandra@promedical.com.au>; Shakespeare, Penny
<Penny.Shakespeare@health.gov.au>
Subject: Re: Promedical POCT [SEC=OFFICIAL]

Hi Penny,

Hope your well.

We have received the TGA approval for our Promedical COVID-19 Rapid Test kit .

Please see the approval certification in the attachment.

Please let me know our next steps.

Kind Regards
Neran

On Thu, 19 Mar 2020 at 12:19 pm, Neran De Silva <neran@promedical.com.au> wrote:
Will do. Thank you

On Thu, 19 Mar 2020 at 12:13 pm, Shakespeare, Penny
<Penny.Shakespeare@health.gov.au> wrote:

Thanks for this Neran, received. Can you please let me know as soon as you hear from the TGA about the outcome of your application for regulatory approval.

Penny Shakespeare | Deputy Secretary, Health Financing Group | Department of Health ☎ 02 6289 3348 | s22 [REDACTED] ✉ penny.shakespeare@health.gov.au

From: Neran De Silva <neran@promedical.com.au>
Sent: Thursday, 19 March 2020 1:32 PM
To: Shakespeare, Penny <Penny.Shakespeare@health.gov.au>
Subject: Re: Promedical POCT [SEC=OFFICIAL]

Hi Penny,

Thank you for reaching out and giving Promedical the opportunity to assist the department of health .

I have addressed the points that you have pointed out below.

Question	Answer
When could ProMedical have its Lateral Flow IgG/IgM POCT available in Australia?	Currently we have a small quantity available. Large quantity can be available in Australia within 10 days of placing the order. And from them we will have a continues supply.
Company description of test for contract purposes	Promedical Equipment Pty Ltd ABN: <u>40 625 347 944</u> <u>5/22 Alexandra Place, Murarrie, QLD, 4172</u> Contact person: Neran De Silva (CEO) s47F
How many tests you can provide in Australia broken done as weekly numbers and for how long, e.g., can you manage X number tests a week for 20 weeks?	Current capacity of 2.5 million test kits per week We can allocate 600,000 - 800,000 pieces per week to Australia for the 20 weeks requested. However the Australian public is our priority therefore we can allocate more per week and for a longer period if required.
Cost per test?	AUD13.90 + GST This may change depending on the performance on the Australian Dollar against the US Dollar.

This may not be the final number as we work tirelessly to increase the production capacity to meet the demands world wide however at the time of this epidemic.

However our priority is Australia and the safety of the Austrian public.

Happy to discuss options if necessary.

Please do not hesitate to contact me if you have any questions or queries.

Kind Regards
Neran

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Hello Neran

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Cost per test?	

Please give me a call if you have any further questions, my contact details below.

Thanks

Penny Shakespeare | Deputy Secretary, Health Financing Group | Department of Health
 ☎ 02 6289 3348 | s22 [redacted] ✉ penny.shakespeare@health.gov.au

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Neran De Silva

M: s47F [redacted] E neran@promedical.com.au
 P: 1300 793 314
 W: promedical.com.au

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THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

SHAKESPEARE, Penny

From: Neran De Silva <neran@promedical.com.au>
Sent: Friday, 20 March 2020 4:49 PM
To: Shakespeare, Penny
Subject: Re: Promedical POCT [SEC=OFFICIAL]

Hi Penny,

As I still expecting the PO as stated earlier? As it's Friday we try to allocated our productions accordingly.

Please let me know.

Kind Regards
 Neran

On Fri, 20 Mar 2020 at 8:53 am, Neran De Silva <neran@promedical.com.au> wrote:
 Hi Penny,

Yes we would like to proceed.
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Yes we can continue discussions for long term agreement.

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Please give me a call if you have any further questions, my contact details below.

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SHAKESPEARE, Penny

From: Shakespeare, Penny
Sent: Friday, 20 March 2020 9:23 PM
To: Neran De Silva
Cc: s22 [REDACTED] Lucchese, Renaye
Subject: RE: Promedical POCT [SEC=OFFICIAL]

That should be fine, we will include 3 April in the contract.

Sent with BlackBerry Work
(www.blackberry.com)

From: Neran De Silva <neran@promedical.com.au>
Date: Friday, 20 Mar 2020, 8:36 pm
To: Shakespeare, Penny <Penny.Shakespeare@health.gov.au>
Cc: s22 [REDACTED] @health.gov.au
Subject: Re: FW: Promedical POCT [SEC=OFFICIAL]

Hi Penny,

Thank you for the request.

We can have the 500 000 units ready for you.
We could try deliver it by the 1st however are we able to set the delivery date as the 3 Ed of April.
Will this possible ?
As we would need to take the delivery time and custom clearance in to consideration.

Please let me know if this dates are suitable for you.
If so we can take your and have that delivered for you.

What would be the delivery address?

Kind Regards
Neran

On Fri, 20 Mar 2020 at 5:30 pm, Shakespeare, Penny <Penny.Shakespeare@health.gov.au> wrote:

Hello again Neran.

On behalf of the Australian Government I would like to procure the following, with payment on delivery:

To be delivered by	1 April 2020
Promedical COVID-19 Rapid Test kit @\$13.90 per test kit	500,000 – to be delivered by 1 April 2020

If you agree please let me know and I will have the contract for formal execution of the agreement tomorrow.

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Yes we can continue discussions for long term agreement.

Kind Regards

Neran

SHAKESPEARE, Penny

From: Shakespeare, Penny
Sent: Saturday, 21 March 2020 8:11 PM
To: 'Neran De Silva'
Cc: s22 [redacted] Lucchese, Renaye
Subject: Commonwealth contract [SEC=OFFICIAL]
Attachments: ProMedical - Department of Health - Goods Contract - 21.03.20 - Execution.pdf

Dear Neran De Silva, on behalf of ProMedical

On behalf of the Commonwealth of Australia as represented by the Department of Health (**Commonwealth**), I wish to offer the attached Goods Contract (**Contract**) for the provision of COVID-19 point of care testing kits.

If you wish to accept our offer for the supply of the COVID-19 point of care testing kits described in the Contract, please arrange to sign the Contract on the execution page (where indicated by your company name) and return a scanned copy of the signed Contract via email today. Our offer is made on the basis the Contract is to be signed 'as is' without any changes to the terms and conditions (including Schedule 1). Please ensure all product details in the Contract are correct. If these details are not correct, please advise and we will amend the contract. If you would like to specify alternative delivery dates, please advise and we will amend the Contract.

Please note that the Contract will not be binding and no legal obligations shall arise unless and until the Commonwealth returns a signed and dated copy of the Contract to you.

We point out that clause 6 of the Contract requires you to provide copies of certificates of currency in respect of all insurances held by you, including product liability insurance. Please provide this to our nominated Contract Officer before 24 March 2020 or, if this is not feasible, then by the date when the first shipment is due.

We look forward to receiving a signed Contract from your company today.

Regards
Penny Shakespeare

Penny Shakespeare | Deputy Secretary, Health Financing Group | Department of Health ☎ 02 6289 3348 | 📧 s22 [redacted]
s22 [redacted] ✉ penny.shakespeare@health.gov.au

s22

From: Lucchese, Renaye <Renaye.Lucchese@health.gov.au>
Sent: Sunday, 22 March 2020 5:36 PM
To: WEISS, David; s22
Subject: FW: Commonwealth contract [SEC=OFFICIAL]
Attachments: ProMedical - Department of Health - Goods Contract - 22.03.20 - Signed.pdf

FYI

From: Shakespeare, Penny <Penny.Shakespeare@health.gov.au>
Sent: Sunday, 22 March 2020 11:35 AM
To: Neran De Silva <neran@promedical.com.au>
Cc: Lucchese, Renaye <Renaye.Lucchese@health.gov.au>; s22 @health.gov.au
Subject: RE: Commonwealth contract [SEC=OFFICIAL]

Thank you Neran

Please find attached a copy of the contract signed by the Commonwealth. We will provide a hard copy to you by mail.

Regards
Penny

Penny Shakespeare | Deputy Secretary, Health Financing Group | Department of Health 📞 02 6289 3348 | s22
s22 ✉ penny.shakespeare@health.gov.au

From: Neran De Silva <neran@promedical.com.au>
Sent: Saturday, 21 March 2020 8:38 PM
To: Shakespeare, Penny <Penny.Shakespeare@health.gov.au>
Cc: Lucchese, Renaye <Renaye.Lucchese@health.gov.au>; s22 @health.gov.au
Subject: Re: Commonwealth contract [SEC=OFFICIAL]

Hi Penny,

Please see the signed contract attached.
Please send the counter signed agreement at your earliest convenience to confirm the order.

Kind Regards
Neran

On Sat, 21 Mar 2020 at 5:11 pm, Shakespeare, Penny <Penny.Shakespeare@health.gov.au> wrote:

Dear Neran De Silva, on behalf of ProMedical

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--

Neran De Silva

M s47F | **E** neran@promedical.com.au

P: 1300 793 314

W: promedical.com.au

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THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH



Australian Government

Department of Health

Mr Neran De Silva
ProMedical Equipment Pty Ltd
5-22 Alexandra Place
Murarrie QLD 4172

By email to neran@promedical.com.au

Dear Mr De Silva

Re: Goods contract for the provision of COVID-19 point of care testing kits between the Commonwealth of Australia as represented by the Department of Health and ProMedical Equipment Pty Ltd

On 23 March 2020 the Commonwealth of Australia as represented by Department of Health (Commonwealth) entered into a written agreement with ProMedical Equipment Pty Ltd (ProMedical) pursuant to which ProMedical was to supply 500,000 Wondfo SARS-CoV-2 Antibody Test Kits (Test Kits) for use in the Commonwealth's National Medical Stockpile (Contract).

The Contract relevantly requires ProMedical to:

1. obtain and maintain all intellectual property rights, licences or other approvals required for the lawful provision of the Test Kits to the Commonwealth under the Contract; and
2. deliver 500,000 Test Kits to the address specified by 3 April 2020.

To date, ProMedical has not delivered any Test Kits to the Commonwealth, or otherwise evidenced that it has all intellectual property rights, licences or other approvals required for the lawful provision of the Test Kits.

We also understand that ProMedical has withdrawn its application for the Test Kits to be included in the Australian Register of Therapeutic Goods (ARTG).

In light of the above, we request that ProMedical urgently (and by no later than **COB Wednesday 20 May 2020**) provide in writing:

1. advice (and supporting documentation) as to whether or not the Test Kits are (or will be) approved and listed on the ARTG;

- 2 -

2. copies of any purchase order, contract, licence, approval, or other evidence to substantiate its ability to lawfully deliver 500,000 Test Kits to the Commonwealth; and
3. an explanation as to the failure to comply with its contractual obligations.

The Commonwealth reserves all of its rights, both under the Contract and at law.

Yours sincerely

s22



Renaye Lucchese
A/g Assistant Secretary
Diagnostic Imaging and Pathology Branch
Medical Benefits Division
19 May 2020

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH



Date: 20 May, 2020

Dear Renaye Lucchese,

Re: Goods contract for the provision of COVID-19 point of care testing kits between the Commonwealth of Australia as represented by the Department of Health and ProMedical Equipment Pty Ltd

In response to your letter sent on 19th May 2020, please see below addressing the information you have requested.

1. Promedical Equipment currently have authorization to import and distribute an ARTG listed Test Kit (ARTG No: 333160). Authorization letter from the Manufacturer is attached.
2. Promedical Equipment are able to lawfully deliver 500,000 test kits to the Commonwealth (ARTG No: 333160) (Australian Government, Department of Agriculture, Water and the Environment Permit: 0004161246).
3. As you are aware, Promedical Equipment withdrew from the ARTG the previous application with the Manufacturer Wondfo, therefore Promedical were at that time unable to supply the test kits. The Procurement Officer with the Department of Health was notified of this by Promedical.

Please do not hesitate to contact me if you require any further information or have any questions or queries.

Sincerely,

s47F

Nerán De Silva
CEO, Promedical Equipment

ABN: 40 625 347 944
(07) 3040 7791



www.promedical.com.au
sales@promedical.com.au



5-22 Alexandra Place,
Murarrie, QLD, 4172



HIGHTOP

QINGDAO HIGHTOP BIOTECH CO.,LTD

No. 369 Hedong Road, Hi-tech Industrial Development Zone, Qingdao, China.
www.hightopbio.com

Letter of Authorization

14 May 2020

To Whom It May Concern,

We, QINGDAO HIGHTOP BIOTECH CO., LTD, located at No. 369 Hedong Road, Hi-tech Industrial Development Zone, 266112 Qingdao, Shandong, People's Republic Of China, authorize PROMEDICAL EQUIPMENT PTY LTD, located at 5-22 Alexandra place, Murarrie, QLD, Australia, to import, market and sell SARS-CoV-2 IgM/IgG Antibody Rapid Test (For Professional Use) in the Territory of Australia (ARTG No. 333160).



Signature *Sarah Yin*

Name: Sarah Yin

Designation: DIRECTOR

Date: May 14, 2020

No. 369 Hedong Road, Hi-tech Industrial Development Zone, Qingdao, China.
www.hightopbio.com



Australian Government

Department of Health

Mr Neran De Silva
 ProMedical Equipment Pty Ltd
 5-22 Alexandra Place
 Murarrie QLD 4172

By email to neran@promedical.com.au

Dear Mr De Silva

Re: Goods contract for the provision of COVID-19 point of care testing kits as between the Commonwealth of Australia as represented by the Department of Health and ProMedical Equipment Pty Ltd

I refer to the above contract (Contract), my letter of 19 May 2020, and your reply letter of 20 May 2020.

The Contract specifically requires ProMedical Equipment Pty Ltd (ProMedical) to supply 500,000 Wondfo SARS-CoV-2 Antibody Test Kits to the Commonwealth of Australia as represented by the Department of Health (Commonwealth).

The Commonwealth has not agreed to ProMedical supplying SARS-CoV-2 Antibody Test Kits manufactured by a party other than Wondfo or otherwise agreed to ProMedical's obligations under the Contract being varied.

In these circumstances, your letter (which suggests that ProMedical is authorised to supply test kits manufactured by Qingdao Hightop Biotech Co., Ltd) does not:

- substantiate ProMedical's ability to perform the Contract; or
- provide a reasonable explanation as to ProMedical's failure to comply with its contractual obligations.

The Commonwealth requires ProMedical to urgently (and by no later than 4pm Monday 25 May 2020) provide:

- satisfactory evidence of its ability to lawfully deliver 500,000 Wondfo SARS-CoV-2 Antibody Test Kits (Required Test Kits) to the Commonwealth, including copies of relevant purchase orders, contracts, licences and approvals; and
- written confirmation that the Required Test Kits will be delivered to the Commonwealth without further delay.

In the event ProMedical fails to do so, the Commonwealth will treat this as evidence that ProMedical is unable or unwilling to discharge its obligations under the Contract and may exercise its resultant right of termination.

The Commonwealth reserves all of its rights, both under the Contract and at law.

Yours sincerely

s22



Renaye Lucchese
A/g Assistant Secretary
Diagnostic Imaging and Pathology Branch
Medical Benefits Division
22 May 2020

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH



Date: 25 May, 2020

Dear Renaye Lucchese,

Re: Goods contract for the provision of COVID-19 point of care testing kits between the Commonwealth of Australia as represented by the Department of Health and ProMedical Equipment Pty Ltd

Thank you for your email. I would like to bring the following to your attention in response to your letter on the 19th May 2020 and 22nd May 2020.

When COVID-19 Virus enters the body, the human body produces two types of antibodies in response. They are IgM and IgG. Detecting these antibodies are the base of any antibody rapid test kit on the market. IgM is the first antibody to be produced and 4-7 days after, IgG will be produced.

Wondfo SARS-CoV-2 Antibody Test (Lateral flow method) only tests for detection of IgG antibody which is produced around 4-7 days after release of IgM antibody. Therefore, if used for early detection, this will give false negatives which in turn is low in accuracy and sensitivity.

Qingdao Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test detects for both IgM and IgG which can be used for early detection as well as late detection making it a much more superior product with a higher sensitivity and accuracy compared to Wondfo SARS-CoV-2 Antibody Test (Lateral flow method). Therefore, we suggest that the Government receives 500,000 of the Qingdao Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test which is ARTG approved and listed for the same price as the Wondfo SARS-CoV-2 Antibody Test (Lateral flow method).

Furthermore, the letter we received from you on the 19th May 2020 requested and I quote '1. advice (and supporting documentation) as to whether or not the Test Kits are (or will be) approved and listed on the ARTG'. This does not specifically state that the product to be included on the ARTG has to be the Wondfo SARS-CoV-2 Antibody Test (Lateral flow method). Therefore, we have provided you with the necessary documentation regarding the approval of the Qingdao Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test, along with the ARTG inclusion and authorization documentation. As mentioned earlier, Qingdao Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test is a much more superior and highly accurate product compared to Wondfo SARS-CoV-2 Antibody Test (Lateral flow method). And we offer the Qingdao Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test at the same contract price agreed in the contract, therefore there will not be any changes to the final price.



We would be pleased to arrange sample Test Kits of Qingdao Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test sent to you to carry out independent testing to compare Wondfo SARS-CoV-2 Antibody Test (Lateral flow method) to demonstrate the higher accuracy, sensitivity and specificity of the proposed Qingdao Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test.

We urge you to consider the Qingdao Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test which is of a higher value at the same price as contractually agreed. We believe this will provide a much better experience to the Australian public and better use of tax payers money.

If this is not the case, we would still be happy to discuss on how we can move forward with supplying the Government with the Wondfo SARS-CoV-2 Antibody Test (Lateral flow method).

Looking forward to hearing from you.

Sincerely,

s47F

Neran De Silva
CEO, Promedical Equipment

ABN: 40 625 347 944
(07) 3040 7791



www.promedical.com.au
sales@promedical.com.au



5-22 Alexandra Place,
Murarrie, QLD, 4172





Australian Government
Department of Health

Mr Neran De Silva
 ProMedical Equipment Pty Ltd

By registered post to 5-22 Alexandra Place, Murarrie, QLD, 4172

By email to neran@promedical.com.au

Dear Mr De Silva

Re: Goods contract for the provision of COVID-19 point of care testing kits between the Commonwealth of Australia as represented by the Department of Health and ProMedical Equipment Pty Ltd

I refer to the above contract (Contract) and our previous correspondence.

Requirements of the Contract

The Contract required ProMedical Equipment Pty Ltd (ProMedical) to supply 500,000 Wondfo SARS-CoV-2 Antibody Test Kits (Required Test Kits) to the Commonwealth of Australia as represented by the Department of Health (Commonwealth) by 3 April 2020.

This obligation has not been amended or varied by the Commonwealth, either to allow for ProMedical to supply SARS-CoV-2 IgM/IgG Antibody Rapid Test Kits manufactured by Qingdao Hightop Biotech Co., Ltd (Qingdao Hightop Test Kits) or otherwise.

ProMedical's inability to perform the Contract

By my letters of 19 and 22 May 2020, the Commonwealth made requests of ProMedical to (within specified timeframes, which have now lapsed):

- advise (and provide supporting documentation) as to whether or not the Required Test Kits were (or would be) approved and listed on the Australian Register of Therapeutic Goods;
- provide satisfactory evidence of its ability to lawfully deliver the Required Test Kits; and
- provide written confirmation that the Required Test Kits would be delivered to the Commonwealth without further delay.

Your reply letters of 20 and 25 May 2020, which concerned the proposed supply of Qingdao Hightop Test Kits, in no way addressed the Commonwealth's requests or evidenced ProMedical's ability to deliver the Required Test Kits.

In these circumstances, and noting that the Contract does not allow for the supply of Qingdao Hightop Test Kits instead of the Required Test Kits, it is clear that ProMedical is either unable or unwilling to perform its obligations under the Contract.

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Election to terminate the Contract and reservation of rights

Pursuant to clause 14(a) of the Contract, the Commonwealth may issue a Notice to immediately terminate the Contract if ProMedical does not deliver the Goods as specified in the Contract (including by any delivery date) or the Commonwealth forms the view that ProMedical will be unable to deliver the Goods as specified in the Contract (including by any delivery date).

By reason of ProMedical's failure to:

- deliver the Required Test Kits to the Commonwealth by 3 April 2020; and/or
- provide satisfactory evidence of its ability to deliver the Required Test Kits to the Commonwealth,

a right of termination has accrued to the Commonwealth under clause 14(a) of the Contract.

The Commonwealth hereby provides Notice of its election to exercise this right of termination. The Contract is now terminated with immediate effect.

Further, through its conduct to date, ProMedical has repudiated its obligations under the Contract. In terminating the Contract, the Commonwealth has accepted this repudiation rather than electing to keep the Contract on foot.

The Commonwealth reserves its rights in relation to the termination of the Contract and generally, including (without limitation) its right to recover any damages suffered by reason of ProMedical's failure to perform its obligations under the Contract.

Yours sincerely

s22



Renaye Lucchese
Assistant Secretary
Diagnostic Imaging and Pathology Branch
Medical Benefits Division
27 May 2020