

 **Pista**

Nitrile Medical Exam Gloves



**WE MAKE  
GLOVES™**



# Specifications

NITRILE MEDICAL EXAM GLOVES

<b>Material</b>	100% Butyronitrile (100% powder free)
<b>Brand</b>	V12
<b>Name</b>	Pista
<b>Use</b>	Medical
<b>USA</b>	ASTM D6319
<b>EU</b>	EN 455
<b>Sizes</b>	S, M, L, XL
<b>SKU</b>	<b>S</b> -12214021 / <b>M</b> -12214022 / <b>L</b> -12214023 / <b>XL</b> -12214024
<b>Sterility</b>	Non-sterile
<b>Color</b>	Royal Blue
<b>Thickness</b>	Avg Finger 4.9mil, Avg Palm 3.8mil

## Description

Our Royal Blue color, V12 Pista Nitrile Exam Gloves are made with 100% Butyronitrile. The average thickness is 4.9mil at the finger and 3.8mil at the palm. V12 Pista conforms with ASTM D6319-19 and EN 455.

# Product Packaging

NITRILE MEDICAL EXAM GLOVES



## BOX:

100 pcs/box

## CASE:

10 Boxes/case

Case size: 35.3x24x26cm

Weight: S 4.8kg / M 5.3Kg / L 5.6Kg / XL 5.8Kg

## PALLET:

84 Cases/pallet

NW: S 403Kg / M 445Kg / L 470Kg / XL 487Kg



# Technical Specifications



**CLIENT:** V12 HEALTH LLC  
33 SW 2<sup>ND</sup> Avenue PH2  
Miami FL 33130  
United States

**Attn.:** Joshua Mendel

<b>Test Report No:</b> 4770317PP01	<b>Date:</b> 08 June 2021
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**SAMPLE(S) SUBMITTED BY THE CLIENT AS:**

V12 Pista Nitrile Exam Gloves, Large, Color: Royal Blue.

**DATE OF RECEIPT:** 12 May 2021

**TESTING PERIOD:** 02 – 08 June 2021

**TEST REQUESTED:** The submitted samples were tested to ASTM D-6319 for nitrile exam gloves for the following:

- 1) Tensile Strength & Elongation (ASTM D-412 / D-573)
- 2) Dimensions (Length, Width, & Thickness) (ASTM D-3577 / D-3767)
- 3) Leakage/Detection of Holes (ASTM D-5151)
- 4) Label Review & Net Count (ASTM D-6319)
- 5) Powder Residue (ASTM D-6124)
- 6) Aqueous Extractable Protein Content (ASTM D-5712)
- 7) Antigenic Protein Content (ASTM D-6499)

**TEST RESULTS:** See pages 2 to 6.

**PREPARED BY:**

**Hayford Mensah, Report Writer  
Packaging & Materials Lab**

**SIGNED FOR AND ON BEHALF OF  
SGS NORTH AMERICA INC.,**

**Frank Savino, Lab Manager  
Packaging & Materials Lab**

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SGS North America Inc.

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# Technical Specifications



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**Date:** 08 June 2021  
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**CLIENT:** V12 HEALTH LLC

**Glove Dimensions Testing**  
 (ASTM D-6319/D-3577/D-3767)

Material: Nitrile Gloves				
Sample	Dimensions		Thickness	
	Length (mm)	Width (mm)	Palm (mm)	Finger (mm)
1	254.54	106.07	0.0780	0.1207
2	251.77	105.50	0.0758	0.1177
3	251.48	106.48	0.0734	0.1180
4	260.20	106.27	0.0816	0.1156
5	253.83	104.65	0.0832	0.1238
6	256.80	106.13	0.0712	0.1342
7	253.34	105.57	0.0664	0.1318
8	250.72	105.23	0.0802	0.1308
9	251.22	106.37	0.0779	0.1185
10	250.75	106.50	0.0772	0.1278
11	255.03	106.69	0.0666	0.1182
12	256.83	105.01	0.0762	0.1299
13	257.32	105.90	0.0656	0.1196
<b>Average:</b>	<b>254.14</b>	<b>105.87</b>	<b>0.0749</b>	<b>0.1235</b>
<b>D6319 Requirements:</b>	<b>230mm</b>	<b>Large: 110mm (+/- 10mm)</b>	<b>0.05 min</b>	<b>0.05 min</b>
<b>Number Failing:</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

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# Technical Specifications



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**CLIENT:** V12 HEALTH LLC

**Tensile Strength Testing**  
ASTM D-6319 / D-573 / D-412

Material: Nitrile Gloves				
Sample	(Before Aging)		(After Aging)	
	Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
---	(MPa)	(%)	(MPa)	(%)
1	23.0	738	19.7	644
2	22.9	718	24.0	681
3	25.4	721	23.3	664
4	21.1	691	26.4	667
5	19.7	698	19.0	637
6	18.4	657	24.5	684
7	23.3	718	20.8	596
8	21.7	708	22.1	644
9	20.2	677	23.4	644
10	19.3	701	22.2	657
11	21.5	688	24.3	654
12	15.8	654	22.8	647
13	26.1	715	21.9	630
<b>Average:</b>	<b>21.4</b>	<b>699</b>	<b>22.7</b>	<b>650</b>
<b>D-6319 Requirements:</b>	<b>14 min</b>	<b>500 min</b>	<b>14 min</b>	<b>400 min</b>
<b>Number Failing:</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

- Notes:** 1) Aging conditions were 100 +/- 2 degrees Celsius for 22 +/- 0.3 hours  
 2) Samples were tested in the lengthwise direction  
 3) Lab conditions were 23°C, Relative Humidity 50%

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# Technical Specifications



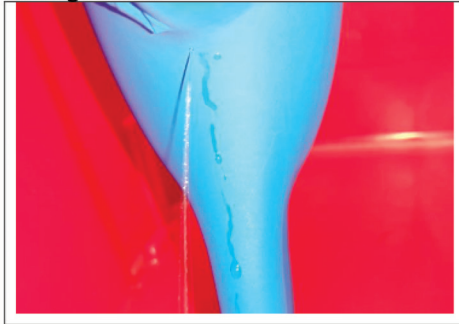
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**CLIENT:** V12 HEALTH LLC

**Detection of Holes in Medical Gloves Testing**  
 ASTM D-6319 / D-5151

Sample	Material	Observation	Results
1 - 500	Large Gloves	7 out of 500 tested gloves have Water Leakage, Droplet or Stream	493 Samples Pass 7 Samples Fail

**Leakage Photo**



**Powder Residue**  
 (ASTM D-6319 / D-6124)

Sample	Total Powder per Glove, mg
Large Gloves	1.24

**Note:** ASTM Method D6124-06 (2017) specifies the procedure to determine the powder content on powder-free gloves. The method specifies 5 gloves are selected for testing. The 5 gloves are tested together as a group and the total weight change is divided by 5 to give the average powder mass per glove. The results for each size shown above is based upon testing 5 gloves per size.

The requirement in D-6319 is a maximum of 2.0 mg.

**Label Review & Net Count Testing**  
 (ASTM D-6319)

Material:		Large Gloves							
Sample	Net Count		Label Review (Section)						
	Claim	Actual Count	9.2.1	9.2.2	9.2.3	9.3.1	9.3.2	9.3.3	9.3.4
---	100	101 - Pass	Pass	Pass	Pass	N/A	Pass	Pass	Pass

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# Technical Specifications



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CLIENT: V12 HEALTH LLC

## Aqueous Extractable Protein Content & Antigenic Protein Content Testing (ASTM D-5712) / (ASTM D-6499)

### ASSAY PROCEDURE:

**Sample Extractions.** The samples were measured, weighed, and cut prior to extraction within a polypropylene extraction vessel. The extraction buffer used was 50 mM phosphate pH 7.4 at a ratio of 5 ml of buffer per gram of sample. The extractions were carried out at room temperature for two hours with agitation. The samples were removed and the extracts centrifuged at >500 xg for 15 minutes to pellet particulates. The cleared extracts were then used in the assay.

**ASTM D5712 Assay.** Proteins are precipitated from the extract by the addition of a DOC-PTA-TCA (DeOxyCholate, PhosphoTungstic Acid, Tri-Chloroacetic Acid) solution and centrifugation. This precipitation step concentrates the proteins and removes substances that may interfere in the assay. The proteins are resuspended in 0.2 N NaOH and then transferred to each of two plates where they are incubated with a (1) copper tartrate solution and (2) an alkaline tartrate solution. Folin Ciocalteu's phenol reagent is added and incubated for 30 minutes for color to develop. The OD of the sample is then determined by reading at 700 nm. The OD values from the alkaline tartrate plate are subtracted from the copper tartrate plate. The resulting values are used to generate the Standard Curve. Protein values for the test items are determined by interpolation from this standard curve. The LOD for the ASTM D5712 assay determined in the laboratory is 2.2 µg/ml and the LOQ is 11.0 µg/gm. An aqueous soluble protein content limit of 200 µg/dm<sup>2</sup> for gloves has been established. (See ASTM D3577 & ASTM D3578.)

**ASTM D6499 ELISA Inhibition Assay.** The standard and test samples are serially diluted in a 96 well plate, after which an equal volume of diluted rabbit anti-latex polyclonal antibody is added and the plate incubated for 2h at 37°C. One hundred microliters of sample from each well is transferred to the corresponding well of a plate coated with Hevea NRL and blocked with non-fat dry milk and incubated for 2h at 37°C. The plates are then washed and a 100 µl solution of Goat anti-Rabbit IgG conjugated with the enzyme HorseRadish Peroxidase (HRP) is added and incubated for 1h at 37°C. Plates are washed and a 100 µl solution of the substrate OPD is added to each well and color allowed to develop. The reaction is stopped by the addition of 50 µl of 4N H2SO4. The plate is then read at 490 nm. Protein values are determined by interpolation from a standard curve.

**RESULTS:** The sample identified as Blue Nitrile Gloves tested below the detection limit of both the D5712 and D6499 assays.

### ASTM D 5712 TEST CERTIFICATE

Weight, gm	Area, dm <sup>2</sup>	Extract Vol, ml	Assay Conc., µg/ml	Total Protein, µg/gm	Total Protein, µg/dm <sup>2</sup>
4.9	10.1	24.5	b.d.		
4.9	10.3	24.5	b.d.	<11	<5
5.0	10.1	25.0	b.d.		

Where b.d. = below detection (2.2 µg/ml)

\*Note: The ASTM D5712 standard defines a "sample" as three items. In the cases where less than three items are provided the test certificate is labeled as "modified".

### ASTM D 6499 TEST CERTIFICATE

Weight, gm	Area, dm <sup>2</sup>	Extract Vol, ml	Assay Conc., µg/ml	Antigenic Protein, µg/gm	Antigenic Protein, µg/dm <sup>2</sup>
5.0	10.0	25.0	b.d.	<0.2	<0.1

Where b.d. = below detection (0.03 µg/ml)

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**CLIENT:** V12 HEALTH LLC  
Sample Photos As Received

<p>Large Gloves</p>	<p>Large Gloves</p>
<p>Large Gloves</p>	<p>Large Gloves</p>
<p>Large Gloves</p>	<p>Large Gloves</p>

\*\*\*\*\*

**End of Report**

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## Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search Back To Search Results

**Establishment:**  
V12 Health LLC  
**Business Trade Name:**  
V12 Health LLC

11400 NW 34 TH STREET  
Doral , FL 33178  
**Registration Number:** 3016842185  
**FEI Number:** 3016842185  
**Status:** Active  
**Initial Distributor/Importer:** Yes  
\*Note Firm May Have Additional Establishment Types.  
Please Review Listings For Further Information.  
**Date Of Registration Status:** 2021

**Owner/Operator:**  
V12 Health LLC  
11400 NW 34 TH STREET  
Doral, FL US 33178  
**Owner/Operator Number:** 10073104

**Official Correspondent:**  
Tarek Kirschen  
11400 NW 34 TH STREET  
Doral, FL 33178  
**Phone:** 1-305-8909900

\* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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## Establishment Registration & Device Listing

FDA Home Medical Devices Databases

1 to 3 of 3 Results for **Owner Operator**  
Number : 10073104

Results per Page 10

New Search

Establishment Name	Registration Number	Current Registration Yr
<a href="#">V12 Health LLC</a> FL/USA	3016842185	2021
<ul style="list-style-type: none"> <li>Medical Gloves With Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs - FORZA</li> <li>Polymer Patient Examination Glove - PISTA</li> <li>Latex Patient Examination Glove - Nero</li> </ul>		Specification Developer
<a href="#">V12 Health LLC</a> TURKEY	3018501299	2021
<ul style="list-style-type: none"> <li>Non-Surgical Isolation Gown - V12 Isolation Gown</li> <li>Gown, Examination - V12 Surgical Gowns</li> <li>Cap, Surgical - V12 Bouffant Cap</li> <li>Cover, Shoe, Operating-Room - V12; V12 Shoe Cover</li> </ul>		Manufacturer
<a href="#">V12 Health LLC</a> CHINA	3018994963	2021
<ul style="list-style-type: none"> <li>Latex Patient Examination Glove - Nero</li> <li>Medical Gloves With Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs - FORZA</li> <li>Polymer Patient Examination Glove - PISTA</li> <li>Patient Examination Glove - CORSA</li> </ul>		Manufacturer

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WE MAKE GL♥VES

**V12 Health, LLC**

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Federal Tax ID # 85-0688159 | FDA registration # 3016842185

"We Make Gloves" is a trademark of V12 Health, LLC

"Everyone Is Essential" is a trademark of V12 Health, LLC

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